Effectiveness of A Filtered Music Listening Programme

To Improve Communication, Social Abilities, and Behaviours in

Children with Autistic Spectrum Condition:

A randomised, controlled trial

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Declaration of Own Work

The University of Edinburgh

I confirm that this thesis presented for the degree of Doctor of Philosophy, Clinical Psychology, at the University of Edinburgh, has been composed and undertaken entirely by myself. I have referenced and listed all sources as appropriate including any quoted text. The thesis has been solely the result of my own work and has not been submitted for any other degree or professional qualification.

Signed Dorothy K. Lawrence

Dated 26 February, 2017

Abstract

The current diagnostic criteria for Autism Spectrum Condition (ASC) rate abnormal sensory sensitivities as being both prevalent and useful in distinguishing ASC at an early age (DSM-5). Parents of children with ASC have often reported that their child's strong sensory reactions can interfere with learning and are disruptive to family life. Filtered music listening programme creators have claimed the programmes "re-educate" the auditory pathway so that sensory overreactions to sound are gradually diminished. The present study was designed to test the effectiveness of a particular filtered music programme, The Listening Programme (TLP), which in trials has been found to reduce abnormal sensory reactions and associated behaviours, and improve communication and social abilities. Sixty-three children aged 4-8 with ASC were recruited for a partial double-blind, randomized, controlled trial. Children were randomly assigned to an experimental group, an active control group (unfiltered music listening), or a passive control group (no intervention). Forty-four children, 15 in each music listening group and 14 in the passive control group, completed all 20 weeks of the study. Children were assessed using the Autism Treatment Evaluation Checklist and assessments measuring autism symptom severity and parental stress. Data were analysed using ANOVAs, ANCOVA's, and supplemented by a visual review of Case Summaries. Between-group differences were not found to be significant at 20 weeks, for Communication but were significant for Social Abilities and Behaviours. At a 40 week follow-up, changes had maintained for the experimental listening group., without any listening for 20 weeks. In comparing mean scores of each group, the active control group, the programme using unfiltered music was consistently less than the experimental group but greater than the control group with no intervention. The results were as predicted, as music listening is used

as a distraction and also as a calming tool by many people. The consistent pattern suggests that the filtered music programme did play a role in improvement greater than music alone. Reported improvements were greatest in areas of sociability, more flexible behaviour, and in physical issues such as continence. Parents in both music listening groups also reported significant stress reduction after the 20-week intervention. Children exhibiting more severe symptoms prior to the intervention appeared to improve most from the music listening. Those children who showed improvement did not necessarily improve in all three areas, consistent with the complexity of sensory sensitivities exhibited in autism. Future research should attempt to more clearly define best responders and utilize assessments that accurately assess sensory reactions and expected outcomes.

Lay Summary

One of the first things that may alert a parent to the possibility of Autism Spectrum Condition (ASC) in his/her child is noticing unusual sensory sensitivities. Parents often report that their child's strong sensory reactions interfere with learning and are disruptive to family life. The creators of filtered music listening programmes have claimed to help sensitive children so their reactions to sound are gradually reduced, helping them to have more normal behaviours and more easily engage socially with others. Studies using brain scans have shown that change does occur in the auditory pathway by consistent listening to elements of sound. This study was designed to test a particular filtered music programme, The Listening Programme (TLP), by Advanced Brain Technologies as in previous studies parents reported that daily listening helped to reduce strong reactions to sound, and improve other associated behaviours. The Spectrum edition used in the study was created for especially sensitive listeners, specifically autism and brain injury. Sixty-three children aged 4 to 8 years with ASC were recruited and were randomly assigned to one of two music programme groups or a group that had no intervention. One of the two music programmes was TLP, Spectrum edition, and the other music programme was created using unfiltered commercial music composed by Mozart. Fifteen children in each music programme group and 14 in the group with no programme completed all 20 weeks of the study. Before the study and after, parents completed three assessments: The Autism Treatment Evaluation Checklist, measured communication, social abilities, and behaviours. The second, the AQ-Child, measured the severity of autism symptoms, and the third measured parental stress levels before and after the intervention. Differences between all three groups were not significant, but both music listening groups had significant change over the 20 week period with the greatest average improvement and largest effect size in the TLP group. Further analysis showed there was also a significant difference between the TLP Spectrum group and the no intervention group for Social Abilities and Behaviours. The trend was consistent across a range of measures, with the largest improvements in the TLP group, lesser change in the unfiltered Mozart group, and little change in the no listening group. Reported improvements were greatest in Social abilities and in behaviours associated with auditory sensitivities with a downward trend in Communications that did not reach significance.. Parents in both music listening groups also reported significant stress reduction after the 20 week study. Some of the changes reported by parents were: “improved eye contact,” “levels of conversation have improved,” “took herself off to bed at 8 pm.,” “holding a conversation for slightly longer,” huge changes in his behaviour, concentration, and also levels of conversation we are now having with him,” “jumped in at swimming this week,” “has started to play football with his brothers unprompted,” “his reading his improved and his social skills are better,” and “ now drawing pictures unprompted and abstractly.” Children exhibiting more severe symptoms prior to the intervention appeared to be those who responded best to music listening. Children who showed improvement did not necessarily respond in all three categories. Future research should attempt to more clearly define the groups of children who respond best and select assessments that accurately measure sensory reactions and expected outcomes.

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1.0 INTRODUCTION

Autism Spectrum Condition (ASC) is a complex lifelong condition with a broad variety of deficits occurring in various combinations from mild to severe in each individual with the diagnosis. The US Centres for Disease Control and Prevention publishes ASC incidence data regularly and the following surveillance summary by Christensen et al. (2016) was published in April of 2016 for the year 2012. Overall estimated incidence of ASC in children 8 years of age was one in 68. Earliest comprehensive evaluation occurred for 43% of children at age 3 years or less and the median age was 50 months overall for earliest known diagnosis. Incidence in 2012 was nearly the same for the estimate reported in 2010. In the UK, Baron-Cohen et al. (2009) used the Special Educational Needs (SEN) register and diagnosis survey to determine the prevalence of ASC in children aged 5 to 9 years and estimated 1 in 64 children would have the diagnosis if directly observed.

Adding to the complexity of the condition is comorbidity, with other disorders seen with the ASC diagnosis. A study by Simonoff et al. (2008) used the SEN register (N=1,515) to identify comorbidity A subsample of 255 was randomly drawn from the SEN group and those meeting the inclusion criteria were assessed for the study. The investigators found that 70% of participants had at least one other disorder identified, and 41% had two or more other disorders. Social anxiety disorder was the most common diagnosis (29.2%), attention-deficit hyperactivity disorder (ADHD) was second (28.2%), and third was oppositional defiant disorder (28.1%). If a child's first diagnosis in addition to ASC was ADHD, 84% received a second comorbid diagnosis.

The primary characteristics of ASC have been defined consistently as deficits in social interaction and communication along with repetitive, restricted behaviours

(RRBs) and interests. Grzadzinski, Huerta, and Lord (2013) have pointed out The American Psychological Association, in its current Diagnostic and Statistical Manual, fifth edition (DSM-5), have now added unusual sensory responses as part of its RRB description. The addition reflects research that identifies abnormal sensory responses as prevalent and useful in distinguishing ASC at an early age. Grzadzinski believes that the new definition will improve research, particularly in helping to identify subgroups within ASC.

Although abnormal sensory responses may be noted by parents in their young child, greater attention has only recently been given to understanding the behaviours associated with sensory abnormalities or to therapies and interventions that may modify these responses. The abnormal responses to sensory input are often observed as upsetting and distracting for the child and disruptive to the daily life of a family. The pattern and strength of the responses is unique to each individual and may be seen in individuals across the spectrum. The shift in recognizing the importance of abnormal sensory sensitivities as seen in the DSM-5 and in their association with other features and behaviours, has led to a greater interest in seeking effective treatments (Hazen et al., 2014), and one treatment, The Listening Programme, (TLP), Spectrum edition, is the focus of this thesis.

Filtered music programmes have been in use since the 1950s with at least 15 different programmes currently available. The term “filtered music listening programme” will be used here to describe recorded music that has been selected for specific features, then filtered and modified for a music album(s). The structured programmes are generally referred to as auditory integration or sound therapies, but contain wide variations in selected music, filtering specifications, various modifications, and programme protocols, which will be discussed later.

The use of filtered music programmes is quite different from what is known as "music therapy", an established clinical discipline according to the British Association for Music Therapy (BAMT, 2016). Music therapy always involves a trained musician who is qualified and registered in the UK by the Health and Care Professionals Council (HCPC). The music therapist normally uses active, improvisatory music-making to relate to their client(s) who may have had injury, illness, or disability. Music is used in an interactive way to build personal connections with the client, in building a therapeutic relationship.

By contrast, filtered music listening programmes use pre-recorded music and are under the supervision of a professional with health or educational training in the areas of occupational therapy, speech and language therapy, special educational needs, or clinical psychology. The recorded programmes are generally used as an adjunct therapy and the newer listening programmes are portable, most often used privately at home, administered by a parent, and supervised by a professional over a prescribed period of time.

1.1 Cognitive Theories of Autism

Many theories of autism have been proposed and tested over the years in an attempt to find and describe a primary impairment. Three cognitive theories, all attempts to understand and describe how children process and use information, remain as central in ASC research. While not a central theory, a Sensory Theory of autism (Bogdashina, 2013) proposes that abnormal sensory reactions interfere with the processing of information, and will be explored later. The three primary theories, all first published more than 20 years ago, are reviewed here briefly to provide background information.

Premack and Woodruff (1978) proposed that if an individual is able to take on another person's mental state or belief, for example to be able to explain and predict behaviour, he has a Theory of Mind. The explanation first appeared to explain deficits found in autism. Numerous types of tests including judging an ASC persons' ability to understand nonliteral language and the ability to read a person's mental state by looking at a person in the eyes or by hearing a person's voice were undertaken. As some individuals with autism did pass the tests, two explanations emerged. The theory explains some but not all aspects of the disorder and second, certain aspects might not be a deficit but are delayed in some individuals.

The Theory of Executive Function was proposed by Ozonoff, Pennington and Rogers (1991). Their definition of executive function was the ability to plan and problem solve towards reaching a future goal, which might include controlling impulses, being organized in planning, being able to inhibit irrelevant responses, and being flexible with actions. The authors examined data from tests given to 23 autistic and 20 neurotypical participants for executive function, Theory of Mind, verbal memory, and emotional perception in high functioning ASC individuals, and selective deficits were found in all categories. Data from Theory of Mind tasks, requiring an individual to attribute a mental state to another individual, were impaired only in a subset of participants, but executive function deficits were universal in the ASC group. The authors suggested that taking the perspective of executive function, which included cognition, behavioural flexibility, and controlling emotion, rather than only a cognitive view, might aid future investigations.

The Weak Central Coherence Theory was proposed by Frith in 1989 (Frith & Happe, 1994), to explain how individuals with autism are often focused on details rather than generalizing and seeing an overview, a global picture. The authors pointed out that

Theory of Mind addressed deficits, but did not address special abilities, such as those observed in savants. The Weak Central Coherence Theory attempted to explain both impairments and savant skills. An example of this was seen when ASC children were given an Embedded Figures Test and scored higher than a group of learning disabled children or a group of normal children. Frith and Happe noted there may be strengths that are not noticed in an ASC child due to the prediction of deficits in a theory. For example a change in context can change an individual's ability. An example was observed in reading individual words correctly, when three autistic groups and a control group all scored the same. However, when the words were in a different context, such as "a big tear in her eye" or "In her dress there was a big tear", the control group scored higher than the ASC groups. Frith and Happe were clear that in the early stages, the theory was still tentative and needed to be examined further.

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Rajendran and Mitchell (2007) reviewed the three theories, to examine how each theory came about, based on the research and ideas at the time. In general, the authors concluded that autism is too complex and creating tests to measure every aspect found in each theory was too difficult. Rajendran and Mitchell question the idea that autism, even with its new definition as a spectrum, might not be distinct, but may overlap with other developmental disorders such as Tourette syndrome, Attention Deficit Hyperactivity Disorder, and Pragmatic Language Impairment.

The conclusion that Rajendran and Mitchell (2007) drew regarding the three central theories is that no integrated account actually describes and explains all the characteristics of autism, and suggest that rather than a disorder, autism may be seen as a neurodevelopmental condition. This change has now come about and autism is often considered Autism Spectrum Condition (ASC), the terminology that is used in this paper. This historical look at autism theories is particularly useful to illustrate the trajectory of ASC research, and how it continues to provide new clues to this complex condition. The authors suggest the three theories be examined as a product of their time and in the future, studies should examine developmental trajectories, as there are different outcomes and different developmental pathways to these outcomes for each ASC individual.

Determining developmental trajectories was the goal of a study by Fountain, Winter and Bearman (2012). Extensive analyses were based on data taken from 6,975 records of children born in California, enrolled in the California Department of Developmental Services, having at least four evaluations in the database, aged 2 to 14 years, and diagnosed with autism. Symptoms related to sociability, communications, and repetitive behaviours were evaluated. Results revealed that many children showed substantial change. Six groups were identified and described as low, low-medium, medium, bloomers, medium-high, and high. Improvement for the “low” group was relatively flat, the high-functioning group improved rapidly, and most of the improvement was noted before age 6.

“Bloomers” was the name given to a group (approximately 10%) that appeared to be in the lowest group at the beginning but at the end were equal to those in the high functioning group in sociability and communication. In children with repetitive behaviours, few showed significant change over time (Fountain et al., 2012). The study was able to provide a closer look at six trajectories and to follow the patterns of development from 1992 through 2001 for the children. The data used did not provide any details on therapies or interventions that might have driven change, but did confirm that developmental change occurred for many of the children, underscoring the need for more research in early intervention and effective treatments.

1.2 A Sensory Theory of Autism

A lesser-known theory of autism began with Kanner and Asperger's observations of patients' unusual reactions to the senses, to touch, taste, smell, sight, and sound. The theory focuses on the abnormal reaction to sensory sensitivities that is now noted in the DSM-5. Bogdashina (2013) writes that a sensory hypothesis was proposed as early as 1949 when Bergman and Escalona wrote in an article published in *The Psychoanalytic Study of the Child*, that children with autism begin life with greater sensory sensitivities. In response, the children learn strategies as a way to protect themselves from sensory distraction, and this results in difficulties in development.

The use of sensory integration to treat sensory dysfunction in the field of occupational therapy has evolved over the years, starting with Ayres, who in 1979 developed a theory to describe sensory processing and its relationship to behavioural deficits. Ayres' therapy was based on supporting a child's basic motivation to play, as explained by Parham et al. (2011). A child would assist in choosing activities, then the therapist would support the child and challenge him or her with tactile, vestibular and proprioceptive sensory opportunities. The activities were designed to support self-regulation, sensory awareness, or movement in space and push the child's sensory thresholds towards a normal range in a safe and pleasurable environment. Ayres reported that sensory processing difficulties are common in ASC children. Although Ayres Sensory Integration did not include any specific treatment for auditory sensitivities, she believed that sensory systems were processed together, and therapy that used sensation to influence multisensory perception would affect learning and behaviour. Ayres' early work was important in laying a foundation for the field of occupational therapy.

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Ornitz (1973) was a psychiatrist who, over 40 years ago, wrote a detailed review of childhood autism including auditory sensitivities. He wrote that if a child does not respond to verbal instruction or certain sounds, he or she may first be taken to a speech and hearing clinic. The child may seek out auditory stimulation, startle to quiet sounds, or become disturbed on hearing specific loud sounds, such as a siren or vacuum cleaner. Ornitz discussed the difficulties of making a diagnosis of childhood autism and suggested one of the problems often missed by a psychiatrist or physician, was the failure to look for hypo- and hyper-sensitivities. He explained the reactions may be hypo- and hyper- in the same person, even producing opposite reactions to the same stimuli but at different times.

This complexity in reactions may mean a result in a clinical test would be accurate one day, but if testing were done on a different day, the opposite results might be reported, making sensory abnormalities difficult to study. The problem persists today, as according to Bogdashina (2013), all the sensory difficulties common in autism have not always been explored and reported, and sensory variables not always considered.

As sensory dysfunction is not specific to autism, other areas have been identified as describing the nature of autism more completely, as seen in the three central cognitive theories described previously. Yet Bogdashina (2013) pointed out that sensory dysfunction has been described as being nearly universal. Sensory symptoms are seen early in development and may be a flag to parents as a first sign of autism. While not specific only to autism, the sensory profiles are likely to differ from those seen with other disorders. More research supportive of a sensory theory, which Bogdashina described as a “new (but old) field,” (p. 5) is cited in the literature review, as it has again emerged as a topic in recent studies. Bogdashina believed that in addition to clinical tests, individual accounts from people with autism have important validity and should be recognized.

A sensory theory of autism lays a foundation for exploring the use of a filtered music listening programme to improve auditory processing, auditory sensitivities, and associated behaviours. It is believed that filtering and other modifications in the listening programme may be able to push a child's sound thresholds towards a more normal range by regular exposure to specific, gentle stimulation.

Investigators have continued to find associations between observed behaviours and abnormal sensory sensitivities, particularly auditory. One study investigated whether abnormal sensory responses would be distinguishing ASC symptoms in young children when compared to other developmental delays. The authors (Wiggins et al., 2009) pointed out that past research about sensory sensitivities was often not undertaken with very young children and that sensory assessments were often given after a child had their first ASC assessment. After the assessments, parents would be more aware of abnormal sensory responses and their significance. The goal for the study was to determine if a first assessment might be able to discriminate ASC children from those with other developmental disorders, to see if there might be important sensory differences that might alert parents of young children to the condition.

Participants were children aged 17 to 45 months (average age 33 months) of 34 families recruited from an early intervention programme. All completed the Short Sensory Profile (SSP; Dunn 1999) after agreeing to participate and no child had yet been diagnosed with ASC. The Autism Diagnostic Observation Schedule (ADOS; Lord et al. 1999) was then used, as well as the Battelle Developmental Inventory (Newborg 1984) to assess mental age. After clinical assessment, 17 children were diagnosed with Developmental Delay (DD) and 17 with ASC. None of the children were typically developing and there was no difference in chronological or mental age between the groups. Analyses of each group using analysis of variance (ANOVA), indicated a significant difference between the ASC and DD diagnosis for tactile sensitivity and auditory filtering (p <.001) and a smaller amount (p = .01) for taste/smell sensitivity (Wiggins et al., 2009). The ASC group scored significantly worse in the auditory filtering domain for behaviours described by the SSP as "difficulty paying attention, lack of response to voice, does not respond to name, and cannot work with background noise" (p.1089).

The small sample size may not have detected other differences, but the authors claim the results were also implicated in prior research of ASC children, suggesting they are relevant to the ASC population. The Wiggins et al. (2009) study is relevant to the present study in identifying auditory filtering as a likely first indication that a child may be diagnosed with ASC, and as one of the worst scoring categories in the profile. Behaviours related to sound as described in the Sensory Profile were used to identify auditory filtering. Determining if abnormal sensory reactions are evident across the spectrum or only found in certain subsets may help to understand who might benefit from intervention.

Sensory abnormalities across age, ability, and IQ levels used to denote low and high functioning, were investigated by Leekam et al. (2007) in two studies. The authors' first study interviewed parents of 33 ASC children aged 24-140 months consisting of 17 high functioning, 16 low functioning, 15 children with language impairment, 19 with developmental disabilities, and 15 neurotypical children. Interviewers asked the parents questions about sensory items from the Diagnostic Interview for Social and Communication Disorders (DISCO, Leekam, Libby, Wing, Gould, & Taylor, 2002; Wing, Leekam, Libby, Gould, & Larcombe, 2002), to determine if the autism groups differed in frequency and in the pattern of sensory abnormalities from the other groups. Groups were matched on age, non-verbal IQ, and verbal comprehension of language.

The researchers found that 94% of the ASC children exhibited sensory symptoms compared with 65% in the other clinical groups and parents reported the abnormal sensory sensitivities were more likely to be for vision, and touch/smell/taste. The ASC children were also more likely to have multiple sensory issues (Leekam et al, 2007). It should be noted the data showed as many of the ASC children had abnormal auditory sensitivities as abnormal vision concerns, but the authors did not include auditory sensitivities in the category of most likely sensory symptoms. They were specifically looking at differences between ASC children and other clinical groups, and auditory sensitivities were also found to a lesser degree in children with developmental disabilities and typically developing children.

A second larger study investigated 200 individuals aged 32 months to 38 years seen at a Centre for Social and Communication Disorders, where nearly all referrals had been diagnosed with ASC and where the DISCO is part of the assessment process. The aim was to determine if differences existed in sensory responses between low and high functioning ASC individuals (as measured by IQ), and in younger and older individuals. Nearly all (92.5%) had displayed at least one abnormal sensory response (Leekam et al., 2007). Abnormalities were more often seen in two or three additional sensory domains, as measured by the DISCO, and were seen regardless of age or IQ. Data over a three year period from the DISCO were coded and grouped by age and IQ levels, and analysed to determine if abnormal sensory responses might be different at different ages. Main findings indicated abnormalities are likely to continue into adulthood although some sensory symptoms may change with age, such as visual and oral symptoms, and IQ. Other symptoms such as abnormal sensitivity to gentle touch may increase with age.

The two studies together provide evidence that sensory sensitivities are more prevalent in children diagnosed with ASC than in children with other disabilities and that the sensitivities occur across age and in low and high functioning groups. The authors (Leekam et al., 2007) stress that more detailed assessments are needed and more information should be given to parents, so they can better cope with the stress and anxiety experienced by ASC individuals. This is especially important for low functioning ASC individuals who cannot explain their discomfort, as they may appear severely disturbed and show aggressive behaviour.

The DISCO was selected for the studies as it highlights sensory symptoms in detail and provides patterns of sensory features found in any child. As the first study was small and groupings for specific domains had small numbers, the authors report that a significance level of $p < .01$ was used to give validity to their analyses. Leekam et al. (2007) point out there may be a connection between social and communication difficulties, and sensory abnormalities, and that more research is needed in this area. The studies provide supporting evidence that abnormal sensory sensitivities are pervasive, are evident in both low and high functioning ASC individuals, and that they do persist over time, although some symptoms may change in severity.

1.3 Autism Research Focus in the UK

A recent study involving stakeholders in the autism community sought to determine if they were satisfied with the allocation of research funds and if their concerns were being addressed by autism research in the UK. Pellicano, Dinsmore and Charman (2014) recruited 14 autistic adults, 27 parents of autistic children, 20 therapists, 16 teachers, and 11 autism researchers in a study using 11 focus groups, 10 interviews conducted with 72 people who were contacts of the researchers, and 1,929 people recruited online from the autism community. The last group included individuals from parent groups, various ASC organizations, and networks of practitioners, and all completed an online survey. Nearly all participants expressed dissatisfaction with current funding patterns for UK autism research. Their replies illustrate a large gap between basic science that is currently studied and the practical everyday concerns participants felt were most important to them. Researchers also agreed that the more immediate needs of autistic people and their families should be addressed and funds more evenly distributed to all areas.

Three sub-themes were identified by Pellicano et al., (2014). The first was services and supports with an emphasis on daily life skills that help an individual with self-management, especially needed when dealing with multi-tasking, anxiety, and with sensory difficulties. Parents were concerned with keeping their child safe, and with teaching them to be independent. One of the areas emphasized by autistic individuals and researchers was lack of information and a desire for a better understanding of sensory sensitivities.

Knowledge about autism was a second sub-theme. Autistic adults, parents, and therapists cited a lack of accurate awareness in the general public and limited knowledge among health professionals. Several parents told of lack of support from a health professional after their child received the ASC diagnosis, leaving them feeling they were now very much on their own (Pellicano et al., 2014). The third sub-theme was research logistics, with researchers pointing out difficulties in obtaining funding, with a need for collaboration, ability to respond flexibly to gaps in knowledge, and the necessity of translating research findings into practice.

In the online survey, all 13 questions posed were rated as of value. “What are the best ways to improve the life skills of autistic people?” was rated as the most important question for research by all family members, practitioners, and researchers (Pellicano et al., 2014). Autistic adults rated this question as second in importance after the topic of public services meeting the needs of those with autism. Three questions in the survey were either of moderate or little importance to their current needs: the incidence of ASC, if the condition might be caused by genetic factors, and if it might be caused by environmental factors.

Survey participants were also asked if they had a specific topic they would like to see researched in the next ten years. Overall the focus was again on research making a difference in everyday lives. Family members and therapists asked for better ways to teach life skills, to promote independence, and to support life transitions. ASC individuals and researchers asked for more information about sensory sensitivities, depression, and anxiety, and family members wanted to know more about medical issues such as gastrointestinal problems (Pellicano et al., 2014).

The study was fairly large, with authors (Pellicano et al., 2014) using several methods to identify the issues: interviews, focus groups, and an online survey. They included relevant stakeholder groups so that views from each could be heard, and asked specific questions about current funding and future needs. Including an open question allowed for different feedback outside of the prepared questions. This study was a very good attempt to examine autism research in the UK outside academia, as the authors reached out to those in need of support and asked directly what the focus of support should be, providing important feedback to the ASC research community. Two requests by participants in the survey (Pellicano et al., 2014) are relevant to the present study: a need for more research on interventions that may improve daily life for ASC individuals, and a need for information about sensory sensitivities.

1.4 Filtered Music Listening Programmes

The field of auditory training using filtered music listening programmes has grown over the past 60 years, largely through individual reports of success in improving abilities and behaviours of children with a variety of dysfunctions. A filtered music listening programme is defined as a structured listening experience in which recorded music has been filtered to remove bands of sound, to focus on the remaining band, often focusing on the frequency band for speech. This is part of a strategy to retrain the brain to hear the remaining sounds more accurately, a bit like being in a crowded room and not quite hearing what a friend is saying, until the rest of the room becomes quiet.

At least 15 filtered and/or modified commercial music listening programmes are currently available and are listed in Appendix A. The programmes come from France, Germany, Australia, Canada, Denmark, the Republic of Ireland, and the US. They generally all claim to improve abnormal reactions to sound and to improve auditory processing, defined as the brain's ability to interpret sound accurately and understand its meaning.

Two French medical doctors who were ear, nose and throat specialists were early researchers in this field: Tomatis in the 1950's (Anderson, 2011), and Berard in the 1960's (Dr. Guy Berard 2016). The many programmes that exist today are known by a variety of names but are often spoken of as auditory integration therapy (AIT), the commercial name of Berard's programme. He later called his own programme Berard AIT to differentiate his work. The programmes are sold commercially, generally by educators and therapists, who attend training courses to learn specific information about using the programmes. Each company makes similar claims but seeks to differentiate itself by explaining how the creator's ideas led to the development of a different and improved programme.

Tomatis's autobiography, *The Conscious Ear: My Life of Transformation Through Listening* (1977, English Edition 1992), describes how he came to experiment with filtering and modifying music, in an effort to improve his patients' ability to sing, speak, and understand sound clearly. Tomatis's programme used music composed by Mozart, which he believed was the most universally enjoyed by all ages and cultures. In order to filter the recorded music, Tomatis developed a device he called the Electronic Ear. The recorded music would enter the Electronic Ear, which allowed the therapist to manipulate a system of filters, depending on the frequency range he/she wanted to emphasize. The music would pass through the filtering system and amplifier and into headphones.

The advent of portable listening equipment, starting with cassettes and cassette players, meant the Tomatis method of filtering, which had been based on individual listening curves as measured via an audiogram, could now be standardized and recorded for music albums. In his book *Listening for Wellness*, Sollier (2005, p. 197) describes the filtering as focusing on three auditory frequency zones. Tomatis had described the zones as he had observed patients' reactions to hearing music filtered within the following ranges: 125 Hz to 1,000 Hz as the body zone, 1,000 to 2,000 Hz as the language/communication zone, and for 2,000 Hz and beyond, as the creativity zone. Sollier, who attended many workshops by Tomatis, explained that filtering isolates and emphasizes each zone as a means of re-educating the ear to hear and process information from each filtered range more clearly and accurately.

Some authors have written about their programmes, and others have written stories of individual successes for a number of dysfunctions, including several writing about success for autism. The Tomatis website (http://www.tomatis.com) claims that 100,000 people benefit every year, that 1,500 therapists and teachers are licensed by Tomatis in over 50 countries, and that 220 schools have Tomatis learning devices ("By the Numbers," 2016, June 15). Another website (http://www.tomatisassociation.org) lists 31 case studies, 48 clinical research articles, 3 studies in progress, 14 meta-analyses and 27 scientific research articles, and all can be read on the site ("Tomatis Research & Publications," 2017).

Berard wrote on his personal website (http://www.drguyberard.com, 2016) that he worked with Tomatis for a short time but felt the method was inefficient and focused too much on emotional aspects related to hearing. He left the Tomatis clinic and spent the next five years developing what is now known as Berard AIT. A book called *The Sound of a Miracle*: *The Inspiring True Story of a Mother's Fight to Free her Child from Autism* by Stehli (1990) created great interest in the US about the Berard method and its possible use for children with autism, at a time when progress was not considered possible in individuals with the condition and little help was available.

The Berard company website (htpp://www.berardaitwebsite.com) claims there are Berard AIT instructors in 14 countries and the method is available in more than 30 countries ("The History of Berard," 2017). The site lists eight studies with one described as a summary of 28 reports and all are available to download from the site ("Published Results," 2017). The website also notes there is a Berard Channel on YouTube. Siri and Lyons (2014) include chapters by Brockett on Berard AIT (chap. 69) and by Doman on The Listening Program (chap. 64) as useful therapies for autism. The latter programme was used in this study.

The large volume of information about the claimed benefits from music listening programmes includes many stories told by a parent or therapist about using the programmes as a treatment for autism. In addition to books and Internet sites, testimonials can be found on YouTube. This volume of information, including the many studies claimed on the Tomatis and Berard websites, is in sharp contrast to the 2011 Cochrane Review. The authors were able to find only seven studies about the two programmes that were both Randomized Controlled Trial's (RCTs) and exclusively for autism. The Review determined the programmes could not be recommended for ASC. Parents who have a child on the spectrum have few options for scientifically validated treatment and many are willing to try a programme if another parent reports his child has had success. Given the field has continued to expand in the past two decades, there is a need to evaluate the reported science behind the different listening programmes, to explore abnormal sensory sensitivities and their association with ASC, and if preliminary studies suggest efficacy, to initiate carefully planned larger trials to determine efficacy of the newer programmes.

1.5 Cochrane Review of Listening Programmes

Cochrane Reviews are read and used by medical and health professionals in many countries as well as being cited in research. The reviews are considered to be unbiased and therefore may influence policies by health individuals and organizations such as the NHS and US health insurance companies. While the reviews are not the only examples of health services research, they do cover a wide variety of topics, such as the review of "auditory integration therapy or other sound therapies for ASD" (Sinha, et al, 2011). Because the review covers only RCT's, Rimland and Edelson point out that other studies do suggest benefits for certain subgroups.

The most recent Cochrane review of the field (Sinha, Silove, Hayen, & Williams, 2011) concluded there was no evidence that auditory integration therapy or other sound therapies were effective for ASC at that time. Only seven studies met the review's inclusion criteria as an RCT, with all participants diagnosed with ASC, narrowing the number of available studies considerably. Additional problems found in the studies were too much diversity in assessments, and unusable data, so meta-analysis could not be conducted. Six of the selected studies using the Berard AIT method date from 1993 to 2000, and one study using Tomatis therapy was published in 2008. The authors also list Samonas Sound Therapy in this category, as a programme developed using the work of Tomatis, but no studies were found meeting the review's criteria.

The three methods listed in the review (Sinha et al., 2011) are similar, according to the authors, as all involve listening to modified music for varying lengths of time. But they note that in practice, each therapist determines his/her own protocols, and may change the treatment for the individual client. The authors pose the concern that although all the programmes claim similar outcomes, there is considerable difference in intensity and exposure, and likely cannot really be compared. A wide age range of participants (3 to 39 years) in the studies reviewed was a concern, as early intervention is recommended for ASC children and this may have influenced efficacy. Only two of the Berard AIT trials were able to report benefits. In the study using Tomatis therapy the language assessment did not find a difference between the intervention and control groups, and behaviour was not measured.

The authors of the Cochrane review (Sinha, et al., 2011) did not recommend further research in this field, based on lack of evidence and methodological problems in the studies reviewed. If future research were to be undertaken, they suggested it should build on existing evidence, and show a high level of efficacy and outcomes that would be useful and relevant to ASC individuals.

Rimland and Edelson of the Autism Research Institute in San Diego, California wrote a response to the editors of the 2004 Cochrane Review stating they strongly disagreed with their conclusions, and their response was included at the end of the 2011 review (Sinha et al, 2011). In their response, Rimland and Edelson stated they had completed a review of 28 papers on the efficacy of AIT. They concluded that based on 23 of the studies, AIT was beneficial to various subgroups. Just three studies reported no benefit, or no benefit greater than the control group, and two studies reported contradictory results. The complete review, called The Efficacy of Auditory Integration Training: Summaries and Critiques of 28 reports, is posted and can be read on the Berard AIT website ("Published Results", 2017, February 3).

For the six studies included in the 2011 review, Rimland and Edelson provided evidence and arguments to show that the Sinha et al. (2011) reviews were flawed and conclude that AIT does appear to be useful for ASC. In their reply to Rimland and Edelson, Sinha et al. (published in the 2011 review) point out that only data from RCTs are used for the review, as the data are likely to provide more validity, that 17 different assessments were used in the six trials making analyses especially difficult, and that every effort was made to find studies that fit their requirements.

The Rimland and Edelson response (Sinha et al., 2011) underscores the need for more carefully constructed trials and a clearer focus on anticipated outcomes. At the time the six AIT trials took place (1993 to 2000), autism was not always accurately diagnosed. The studies were not clearly defined by age groupings, and the characteristics studied were varied. Much more is known about autism as a spectrum condition today including the prominent role sensory sensitivities play in a child's ability to cope. The Cochrane report concluded by providing solid guidelines and recommendations for future research that would address the limitations of these early studies, and these guidelines were carefully reviewed and incorporated into the present study design.

Only one study of the Tomatis method for ASC (Corbett, 2008) qualified for the Cochrane Review, and later Gerritsen (2010) created a reanalysis of the study by viewing the participants as individual case studies. He first reported on the shortcomings of the original study, citing the small size, the heterogeneous sample, the lack of reporting all results, and the cross-over design, as flaws. He pointed out that Tomatis estimated approximately 60% of ASC individuals respond to the method, so given the small size of 11 participants, data analysis of all participants was unlikely to show positive results. Six children received the Tomatis treatment first, followed by the placebo treatment. Results of the Tomatis therapy are expected to continue to build after the protocol is completed, meaning the cross-over study design should not have been used, as it likely affected the results of the placebo treatment when the treatment followed the Tomatis therapy.

Gerritson (2010) notes there were five children who did not seem to benefit from the Tomatis therapy. For the six children who did respond, an average of five significant improvements each were noted. Gerritson provided pre and post test scores for children who responded, shown in tables to illustrate which outcomes were significant as measured by the Vineland Adaptive Behaviour Scales (VABS; Sparrow, 1984) and Short Sensory Profile (SSP; Dunn, 1999) at a 95% Confidence Interval (CI). While improvements varied with each child, they were noted in daily living skills, socialisation, motor skills, and reductions in hyperactivity. Gerritson's reanalysis points out one of the basic problems with all trials for listening programmes, that it is not yet possible to determine who might best respond to the intervention. There is still a wide variation in assessments used and at times parents and therapists may report improvements that are not noted in standardized assessments. No follow-up assessments were reported for the study. The Cochrane review and efforts to challenge results are presented to show the history of listening programmes. In spite of the outcomes, programme usage among therapists continues and parental reports of success persist.

1.6 Is Filtering Necessary?

Two studies testing the effects of filtered music listening interventions (Bettison 1996; Porges et al., 2014) found the same music without filtering or modifications, created as an active listening control, had the same or nearly the same effect as the filtered music listening programme tested in the trial. Given the lack of evidence for this type of programme, testing the effect of unfiltered, recorded classical music, as an identical structured listening programme, is an important element of the present study.

The first was an early study by Bettison (1996), who compared the Berard auditory training programme with the same music that was unmodified and under the same conditions. Eighty participants, 40 in each group, ages 3.9 to 17.1 years, all had a diagnosis of ASC, or significant autistic symptoms, and showed hypersensitivity to sound based on a Sound Sensitivity Questionnaire, a version created from the Hearing Sensitivity Questionnaire (Rimland, 1991) for the study. Listening sessions were conducted for 10 consecutive days with two half hour sessions daily, at least 4 hours apart. Assessments included: the Autism Behaviour Checklist (ABC: Krug, Arick, & Almond, 1988), the Developmental Behaviour Checklist (DBC; Einfeld & Tonge, 1991a, 1991b, 1995), the Peabody Picture Vocabulary Test (PPVE: Dunn & Dunn, 2981), the Leiter International Performance Scale (LIPS; Leiter, 1980), the Sensory Problems checklist (SP; Edelson, 1992), and scores from an audiogram. All were completed before and at 1, 3, 6, and 12 months after the intervention. Both groups were found to be similar before the intervention.

The study was carefully conducted to be sure no one involved knew the listening allocation. The investigator (Bettison, 1996) also asked if the parent expected an effect from both programmes and parents indicated they did not expect an effect from the structured listening, only the Berard programme. Analyses of the data, including *T* tests for paired samples, were completed to determine differences, and scores on all measures had improved significantly for both groups one month later, with 72.5% in both groups having moderate to marked improvement. Improvements were reported as more appropriate speech, less distress, and seeking more social interaction. The improvements were maintained except for several differences, for example results for the LIPS (Leiter, 1980), a non verbal measure of intelligence, showed a significant increase at 3 months follow up for the Structured Listening group and a significant increase at 12 months for the Auditory Training group. The Structured Listening group showed improvement in sensory processing at 6 and 12 months follow up, but no continued improvement was noted for the Auditory Training group. A comparison at 12 months of the LIPS, PPVT, SSQ, and audiogram scores showed there were no significant differences between the Auditory Training group as compared to the Structured Listening group.

The second study to provide similar results with filtered and unfiltered music was by Porges et al. (2014), and was conducted using his filtered music programme, the Listening Project Protocol (LPP), to document the effect of the programme on auditory hypersensitivities. Porges developed LPP for his research, using music with vocals and a listening protocol of one week, with 45 minute listening sessions conducted daily. Listening took place through headphones in a research room with toys for the children to play with, and parents were allowed to be present.

In the first trial, participants were randomly assigned to a filtered music group or a control group where children wore headphones without music. A parental questionnaire was used to measure behavioural change. Significant improvements were reported in the LPP group in trial one (*p* = 0.007) for listening, auditory sensitivity, spontaneous speech, and behavioural organization as compared to the headphones only group (Porges et al., 2014). To determine if the improvements could have been related to simply listening to the music rather than the filtering, a second trial contrasted filtered music (n = 50) with unfiltered music (n= 32) in the same conditions.

Results of the second trial indicated the improvements also reported in trial one of spontaneous speech, listening, and behavioural organization, appear to have been related to unfiltered music listening. Data suggesting that filtering the music might be the cause of a significant reduction in sound sensitivity (*p* = .040, and in emotional control (*p* = .019). For those children who had auditory sensitivities before the trial and who had improved, an increase in social behaviours was reported and observed from video data taken from a subset (n=61) of participants (Porges et al., 2014). The video was taken for a 10 minute period of semi-structured play before and following the 5 day programme. The play protocol required a child to engage in a joint activity, and observers used the Social Interaction Coding Scale (SICS; unpublished) to observe and quantify sharing behaviour. Children who had improved in hearing sensitivity were the only participants who also showed increased sharing behaviour (*p* = .005). The authors reported the children were receiving other treatments at the same time and several were receiving daily behavioural therapies, which may have influenced the outcomes.

Protocols for the Berard and Porges interventions were short, 10 days and five days respectively, both interventions used different styles of music, and trials for both were conducted in a quiet, separate clinical setting rather than in the home. The LPP trial did not have a long term follow-up so it is not known if the reported effect of reducing hypersensitivity was lasting. The two studies show the importance of comparing a similar unfiltered programme with the intervention, as structured listening to unfiltered music has also been shown to have benefits.

1.7 Listening Programme Usage

Filtered music listening programmes fall under the category of Complementary and Alternative Medicine (CAM) treatments. Parents may use CAM because they want to help their child and know that studies show early intervention is important, yet they find that few options exist for proven treatments for ASC. Parents are often willing to try a CAM treatment if they perceive it is not harmful, is plausible based on the creator's theories, and they have read or heard it is effective for some children. Christon, Mackintosh, and Myers (2010) created an Internet survey to examine usage, expectations, cost, and other issues that parents were asked to assess in their use of CAM treatments in the US, where universal health care is not provided.

Participants (n=248) were parents of ASC children ranging in ages from 21 months to 21 years. Results from the survey (Christon et al., 2010) indicated that 71% of respondents (n=176) had used CAM, 40 parents had used AIT and 41 had used music therapy with over half reporting some or much improvement. (It should be noted that the term AIT is used for a specific programme as well as for the whole field, so the usage is not necessarily for only Berard's AIT programme.) Parents reported their sources for recommendations on choosing a programme were from other parents (40.3%), the Internet (40.3%) and the child's medical providers (39%). Parents generally believed their child would make at least some improvement from the intervention and across the various treatments, 4 in 10 reported "some improvement" (p. 252). Cost of the treatments was reported by 44.7% to be difficult to meet. Parents reported stopping treatment first if they felt it did not work, and second if the treatment was too expensive to continue.

The survey was small and limited to parents who were able to reply by computer, and who were already members of an autism organization in the US, which may have affected the outcome. Parents who would pay to use CAM treatments would likely do so believing it would help their child, which might influence their evaluation of the therapy. Children often are involved in a number of therapies at the same time and this possible influence was not evaluated in the study. The main conclusion of the small CAM study remains valid, that more research needs to be done for CAM treatments, as families are spending time and financial resources for interventions, including listening programmes, that may not have been proven to help their child.

1.8 Present Autism Listening Study

The present study was undertaken with The Listening Program® (TLP), Spectrum edition, created by Advanced Brain Technologies (ABT). There is no published book specifically about the programme. Primary information is from the website, which states the programme was created for individuals with sensory sensitivities including autism, in need of an intervention (ABT, 2016, June 20) and is available only through trained therapists, health care professionals, and educators. Additional information is provided to professionals who attend training sessions. The company was founded in 1998, released its first listening programme shortly after, and since then over 8,000 professionals have attended a paid training course for the programmes, which are reported to have an estimated reach of one million listeners since the first was created (personal communication A. Doman, CEO of ABT, 12 April 2016.) The programmes are available in more than 35 countries and the company have representatives in Bulgaria, Colombia, Germany/Austria, Israel, Japan, Mexico, Russia, Singapore/Malaysia, South Korea, and the United Kingdom and Ireland.

A US health insurance company, TRICARE Extended Care Health Option, recently approved payment including listening equipment and a therapist's time to oversee the programme, for qualifying individuals with special needs, including autism (ABT, Tricare, 2017). A webinar introduction for families or professionals by ABT, a video library of interviews with therapists and parents, and a variety of monthly programmes on TLP Radio are available as recorded Podcasts. Some of the radio programmes have focused on autism, including an interview with an audiologist on autism and auditory hypersensitivity (ABT, TLP Radio, 2017).

TLP Spectrum, the experimental programme for the study, is not mentioned in the Cochrane review, and, to my knowledge, the present study is the first randomized controlled trial with TLP undertaken with ASC individuals. Previous studies show a positive trend in improving communication, social abilities, and abnormal behaviours in ASC individuals, and will be examined more closely in the literature review. In personal interviews previously undertaken by the investigator, parents reported the same improvements and gave insights into the changes in family life because of the programme. It was determined that the next step should be an RCT.

The aim of the study was to determine the effectiveness of TLP Spectrum as it is currently used. The present study has characteristics of both efficacy and effectiveness trials, which are generally considered the first two steps in the creation and evaluation of an intervention in health care research. The intervention has already been developed, and has been used widely for ASC and other auditory related difficulties for nearly two decades. Protocols such as daily listening times have already been established. The intervention has commonly been used in a home setting and overseen daily by parents, with implementation supported by a trained therapist or educator. However, while trends have indicated positive results in a number of studies, there has not been a randomized controlled trial to establish efficacy.

Because of the characteristics of the present trial, that the setting was not controlled, usage was not overseen by a trained therapist or undertaken in a clinical setting, the trial most closely resembles an effectivemess trial, one undertaken under "real world" circumstances.. The participants were representative of the broad spectrum of children aged 4 to 8 years who had been diagnosed with autism by a qualified health professional. Each family had its own unique set of circumstances and challenges in implementing and using the intervention and fitting listening times into their daily schedules.

The study design addressed these primary research questions. Would the experimental programme produce observable and measureable improvements in communication, in social abilities, and improved behaviours, in ASC individuals greater than a control group with no listening? Would similar commercially recorded music that is not filtered or modified create similar change? Would any changes seen after 20 weeks using the listening protocol maintain?

The intervention is not presented as a cure for autism. It is presented as a potential tool that may modify abnormal sensory sensitivities, particularly auditory filtering and hypersensitive reactions to sound as observed by any changes in associated abilities and behaviours. It is proposed that a child who is free from the constant distraction of overwhelming and confusing sensory input, can more easily function to the best of his or her abilities.

2.0 Literature Review.

The literature review will examine a number of elements relevant to listening programmes and their usage for children with ASC. A young parent may not understand the variety of ways that sensitivity to sound may affect their child throughout the day. Several studies will examine the impact in daily life, such as the possible impact on toilet training (Yip et al., 2013). Reports by ASC individuals of all ages are presented to give an "inside look" at how the sensitivity may be experienced, and various ways an individual may learn to cope with the intense experience. The science proposed by the two medical doctors who created the first listening programmes are reviewed to see if their ideas are still relevant today. Preliminary trials using TLP are examined to provide support for the use of the programme in the present study.

2.1 A Conceptual Model for Sensory Processing

In order to treat what were seen as sensory processing difficulties, Dunn (1997) proposed a conceptual model so that associated behaviours of young children could be observed and measured. The model suggested habituation was the simplest way the brain works to interpret sensory input. For example, a child puts on a shirt and must habituate to how it feels. If the brain continues to say it is uncomfortable, a child may be distracted and focus on it all day. Another important process is sensitization. The brain must recognize when the sensation is important and possibly harmful, and when it is not. If either of these functions are abnormal, if a child reacts too quickly, he/she is said to have a low threshold for the sensory experience. If he/she takes too long to react, the threshold level would be considered high. If an individual is tired, stressed, or in a new environment, thresholds may change.

In 1992 Dunn and colleagues used the model to build the 125-question Sensory Profile, as a way to view a child's threshold for sensory input. The features were reported by parents, teachers, and children, and described the frequency of various responses to sensory stimuli that a child might experience during the day, on a 5 point scale ranging from *always* to *never*. Dunn reported that several response patterns emerged that suggested possible effective intervention. These were named *poor registration, sensitivity to stimuli, sensation seeking, and sensation avoiding.* When testing the profile, the investigators found a higher rate of abnormal behaviours listed in children with autism, ADHD, and those with tic disorders as compared to children considered typical, without disabilities (Dunn, 1997). This suggested the Sensory Profile might be helpful to diagnose and plan interventions for children with disabilities. The assessment also continues to be used in research as is often noted in studies cited in this paper. The profile includes a short section on auditory behaviours, but a dedicated assessment to identify patterns associated with abnormal responses to sound in daily life would be a useful measure.

2.2 Behaviours Associated with Sensory Dysfunction

Other studies have continued to investigate which of the sensory processing domains were significantly different in ASC children and if significant differences also existed in sensory processing behaviours between ASC and neurotypical children. Tomchek and Dunn (2007) created a retrospective study using data collected for 281 ASC children ages 3 to 6 at an ASC diagnostic centre, and data taken from a national study for 221 neurotypical children. The 38-item Short Sensory Profile, (SSP; Dunn 1999), a parent report on adaptive behaviours within seven categories using a 1 to 5 point Likert scale, was part of the data.

The authors reported that 95% of the ASC children showed some degree of sensory processing difficulty and that 83.6% had indicated *definite difference* scores in sensory processing (Tomchek & Dunn, 2007). They describe the ASC children as responding differently than neurotypical children to sensory experiences, on 92% of the items at a significance level of $p < .001$, and that their sensory reactions related to overall adaptive behaviours. The greatest differences between the two groups were reported in the sections labelled *difficulty with filtering auditory input, difficulty with tactile input,* and *under-responsive/sensory seeking*. In the *Auditory Filtering* category in this sample, an ASC child might be described as, *Is distracted or has trouble functioning if there is a lot of noise around* (52.0%), *Appears to not hear what you say* (73%), *Doesn't respond when name is called but you know the child's hearing is OK* (51.2%), and *Has difficulty paying attention* (79.0%) (p. 196). A smaller number of children in the *Auditory Filtering* category might be reported as being unable to work with background noise (12.5%), and if there was background noise such as a radio being on, they might have problems completing tasks (16.4%).

The study was large enough to provide evidence of significant differences between the two groups of children ($p < .000$) in total score and all SSP sections (Tomchek & Dunn, 2007). A MANOVA for the ASC group showed the largest effect size for difference in Auditory Filtering (F (1,502) = 845.86, Eta squared = .628). The authors note that behavioural observations were used to indicate abnormal sensory sensitivities, and that additional research with neurophysiological evidence is needed to provide validation of the connection between sensory responses and observed behaviours. The findings provide supporting evidence for abnormal sensory sensitivities, support for the perceived relationship between sensory issues and adaptive behaviours, and for a high incidence of abnormal auditory responses in ASC. The findings also concur with accounts by ASC individuals describing their reactions to sensory input and how it affects their daily lives.

2.21 Daily life skills and toilet training

While it is easy to associate auditory filtering with language and communication skills, the effects of abnormal auditory filtering, including hypersensitivity to sound, may extend to difficulties with daily life skills. In order to understand any changes that might occur with intervention, it is useful to investigate behaviours that have been associated with abnormal sensory sensitivity, particularly auditory filtering. One of the difficulties in measuring and comparing change in filtered music listening programmes, as cited by Sinha et al. (2011) in the Cochrane review, was too many different assessments used across different studies. As sensory sensitivities are currently identified by behaviours, the topic of what behaviours should be assessed for determining efficacy of a listening programme is relevant to the present study.

Toilet training is one example of a self care skill having elements that may be difficult for a child with sensory difficulties and is often delayed in ASC children (Yip, Powers, & Kuo, 2013). Teaching hand-washing techniques, cleaning up, and habituation are generally used for toilet training, but not all children respond, impacting family life in their daily routines, financially with the cost of nappies/diapers, and in activities outside the home including at school. Sensory difficulties with sound, touch, smell, and proprioception are described and associated with abnormal behaviours that an ASC child might exhibit. These might include a number of reactions identified by Yip as reacting to the sound of water in a basin or flushing toilet, not being aware of dirty or messy hands or of wet or soiled underpants, being upset at the smell of urine, the cold feel of a toilet seat, and so on.

Authors Yip, Powers, and Kuo (2013) propose that a sensory-neural approach in toilet training issues, in addition to training behaviour, may affect success as well. They provide two case studies of male siblings with ASC, ages 10 and 5 years, and report on an effort to utilize a training protocol for toileting for both. The protocol is well defined and described in detail by the investigators, including familiarizing the children with the routine, reinforcing the bathroom as a friendly place, praising and rewarding successes for voiding.

The children were assessed with the Sensory Profile (SP; Dunn, 1999) and the Sensory Processing Measure (SPM: Parham & Ecker, 2007), commonly used for children ages 3-10 years for sensory processing abilities. Both children had deficits in multiple areas including difficulties with auditory processing. The older child's scores were interpreted as *some problems* in five categories and *definite dysfunction* in 3 categories, and the younger child's scores were interpreted as having *some problems* in seven categories with one category in *definite dysfunction*. After four weeks of the training protocol, both children achieved success in voiding, but the older child, who showed more profound and complex sensory issues, was unable to successfully achieve independent toileting.

The authors (Yip, Powers, & Kuo, 2013) conclude that toileting may be affected by abnormal sensory responses and this should be considered in addition to usual toilet training protocols. The paper is cited here mainly because of its description of the sensory influences related to toileting, which are often unacknowledged. Only two case studies were explored but both are described in great detail, suggesting how the sensory difficulties identified by the assessments might affect daily routines, including toileting. Standard training protocols were thoroughly outlined as implemented for the two children as described above. The authors used The Sensory Profile (SP; Dunn, 1999) to carefully examine sensory processing factors that may have been different for each child and found a correlation between abnormal sensory sensitivities and lack of desired outcomes in toilet training. The authors recommended that further research in toilet training should address sensory dysfunction in addition to operant conditioning. They emphasize that the issue is prevalent but not openly discussed, and has a profound impact on ASC children and their families.

As mentioned above, it is easy to understand how sensory difficulties described as auditory filtering might interfere with developing communication skills. But other abilities and behaviours associated with abnormal sensory sensitivities may not seem obvious. Other studies have suggested that in addition to toilet training, these might include memory and prediction (Gomot & Wicker, 2012), anxiety levels and health (Mazurek et al., 2013), and restricted and repetitive behaviours (Lidstone et al., 2014).

2.22 Memory and prediction

The recent proposal that sensory overload creates an unpredictable world was based on an extensive review by Gomot and Wicker (2012) of how an ASC child interacts with his or her environment. For a typically developing individual, memories guide behaviour and help to create an appropriate response to any new sensory input. This ability is particularly demanding in social situations, which may present complex multi-sensory information that needs to be processed and evaluated quickly, such as facial expressions in addition to speech.

To support their proposal, Gomot and Wicker (2012) began with reporting clinical observations of unusual reactions to sensory stimuli. They cite several studies of auditory processing including Leekam et al., (2007); and Tomchek & Dunn, (2007) that confirm abnormal auditory activity in ASC, and are also reported in detail in this paper. Gomot and Wicker also reviewed information about brain function and possible relationships between the brain and behaviour, as the brain must process complex sensory information very quickly in order to guide the appropriate behaviour.

The authors (Gomot & Wicker, 2012) suggest that remembering and processing information about the context of an experience is crucial to understanding, guiding, and predicting behaviour. The inability to create flexible predictions about the appropriate communication and action required for the experience, may lead to the inability to adapt quickly, and this can be especially compromising in social situations. The coping strategy might be to minimize change, to attempt to limit interests, to repeat behaviours, or to avoid a situation altogether, to create a known world rather than one that is so unpredictable.

At an early age when memories should be created that will help a child learn ways of coping with the world, the authors (Gomot & Wicker, 2012) suggest that abnormal sensory reactions may be one of the main factors that impedes memory, prediction, and the ability to tolerate change. The authors note that different reactions, hyper- and hypo-sensitivities under different circumstances in the same individual, may add to a child's confusion and distress. Schedules, predictable behaviour, and clear rules may provide comfort for a child, but fall short in social situations when an individual is expected to understand and adapt to changing conversation cues and unpredictable actions of others. Gomot and Wicker's theory of an unpredictable world adds to a sensory theory of autism, by associating abnormal sensory reactions with the inability to acquire detailed and accurate memories, and consequently being unable to predict events and actions based on these memories. All are needed to develop flexible social skills.

2.23 Anxiety levels and health

In addition to the core symptoms of the condition, individuals with ASC and their parents often report a number of health and behaviour difficulties. Mazurek et al., (2013) wanted to determine if there was a relationship between anxiety, sensory processing difficulties, and gastrointestinal (GI) problems, as all three are reported to commonly occur in ASC. They recruited 225 children and adolescents with ASC, ages 2 to 17 years, from a network of 17 autism centres across the US and Canada with the aim of examining a year-long course of parental reports of abdominal pain using the GI Symptom Inventory Questionnaire. Sensory over-responsiveness was measured with items in the Short Sensory Profile (SSP; Dunn 1999) that were relevant to over- rather than under-responsiveness or sensory seeking, and that may refer to reactions to light, sound, or touch. Anxiety was measured with the Child Behaviour Checklist (CBCL; Achenbach & Rescorla, 2001).

Both medical and behavioural measures were assessed at enrolment and at the first year follow-up visit. Results of the data showed that sensory over-responsiveness was significantly correlated with anxiety ($p < 0.0001$) and was also a significant predictor of chronic abdominal pain, constipation, bloating, and nausea ($p < 0.0001$). Results suggest the three difficulties, anxiety, sensory over-responsiveness, and GI problems, may be interrelated for children with ASC (Mazurek et al., 2014). The study indicates the importance of clinicians understanding the relationship of the three factors in planning for assessment and treatment. The investigators suggest that addressing abnormal sensory sensitivities and/or anxiety may have beneficial effects on the GI problems and affect a child's health. Many studies, including this one, rely on parental reports, and this is listed as a methodological limitation. However children with ASC often have communication difficulties, so parents are often the sole providers of information.

2.24 Restricted and repetitive behaviours

Lidstone et al. (2014) conducted two studies to explore abnormal sensory reactions and their relation to restricted and repetitive behaviours (RRBs) in ASC. Their first study was to confirm findings using the Repetitive Behaviour Questionnaire (RBQ;

Turner, 1995) with a sample of 120 ASC children, as the questionnaire had previously been investigated only with neurotypical children. The results supported previous findings that Repetitive Behaviours consist of two subtypes: repetitive sensory and motor (RSM) behaviours, and insistence on sameness (IS), such as engaging in routines and rituals. The results confirmed that internal consistency was high and the factor structure similar, and that the questionnaire was a suitable measure for the ASC sample aged 2 to 17 years.

The second study was comprised of 49 children and adolescents aged 3 to 17 years 9 months who had participated in the first study. The aim was to investigate the relationship of the two subtypes with anxiety, as well as assessing the contribution of abnormal sensory sensitivities (Lidstone et al., 2014). Assessments in addition to the RBQ-2 (Leekam et al., 2007) included a Sensory Profile (SP; Dunn, 1999), a Spence Anxiety Scale (SCAS-P; Spence, 1998) and a pre-school version (PAS, Spence et al, 2001), and a language questionnaire to estimate language abilities. Analyses of the data determined that anxiety correlated with IS behaviours (p = .02), which would include narrow interests, rituals, and rigid routines, and anxiety was associated with sensory sensitivity and sensation avoiding (p < .001). Anxiety levels did not correlate with repetitive motor behaviours (RMBs), such as hand flapping and spinning, however seeking or avoiding sensation did correlate with RMB's. Age and language ability were not found to be significant factors in the results. Abnormal sensory sensitivities may explain the relationship with anxiety according to the authors, and RMB's may help a child to regulate arousal, as a way to lower anxiety.

The study described above cannot confirm causation (Lidstone et al., 2014), but gives insights into the relationship between the factors examined and is another step in understanding the possible effects of abnormal sensory responses on the health and behaviours of an ASC child. Results also illustrate how complex the disorder is, showing that identifying the subset of repetitive behaviours may help to understand and influence which child may respond to an intervention. As with many studies in ASC, the participants were verbal, and/or higher functioning (75% reported complex grammatical speech), and predominantly male (110 males, 10 females). Further research should test the relationships between behavioural subtypes and sensory sensitivities, and their effect on anxiety, as this may help to make any intervention more effective. Associated behaviours are not always assessed, so it will be useful to determine if they improve as well as abilities and behaviours viewed as a direct reaction to sound sensitivity and auditory filtering.

2.3 Individual Accounts of Coping with Sensory Overload

Research evidence documents the existence of sensory issues but hearing first hand accounts provides another perspective, making the experiences far more real and providing rich details that might not emerge in a clinical testing environment. This knowledge is essential as it give insights into how different the experiences are compared to a neurotypical experience, how the individuals learned to cope, and how a parent might modify the environment and help their young child to cope.

One of the earlier reports of first hand accounts was given by O'Neill and Jones (1997), who found published stories and quoted personal difficulties with sensory input. They expressed caution and suggested researchers should be sceptical of the personal accounts, as the writer may have been influenced by the interpretation of another person or by their own theories in telling these stories. A wide range of responses to different sensory experiences were reported. Teeth grinding, humming, singing a repetitive tune, and/or tapping were reported by some individuals as a way to keep consistent loud noise from overwhelming them. Turning off kitchen appliances in order to taste something was a reported coping mechanism for one individual, who wrote of the inability to absorb information clearly from more than one sense at a time. Another sensory issue was having deodorant smell so strong the individual couldn't stand it, and another individual reported having blurred eyesight that interfered with accurate movement and spatial location. One account described multi-sensory experiences, describing them as sometimes sound coming through as colour, and that sensory channels would get confused.

While O'Neill and Jones (1997) had expressed caution in accepting the sensory descriptions of the ASC authors of the published stories, they do accept that the accounts may be realistic. They suggest that much more work needs to be done on this topic and raise many questions that have since been addressed in some of the studies cited above. As more high functioning individuals have reached adulthood, more recent reports support these early self-reports as being significant. The O'Neil and Jones paper was valuable in beginning a discussion about the very different sensory experiences reported by ASC individuals.

2.31 Early high functioning individual accounts

More recent personal accounts support the view that behaviours often perceived as unusual, are engaged in by an individual with ASC as a way to help increase or decrease too much sensory stimulation. For example, Elwin, Ek, Kjellin and Schroder (2013) interviewed 15 high functioning ASC individuals aged 19 to 55. Participants had to be at least 18 years of age, have a good command of the language, in this case having fluent speech and a good understanding of spoken Swedish. This was necessary due to the aim of the study, to gather a full description of each individual's reaction to sensory input in his or her daily life. Topics were planned in advance and discussed with each participant, with efforts made to keep questions both concrete and open-ended.

Interviews with the eight women and seven men were recorded, transcribed, and coded for categories. Some participants gave concise answers while others gave long answers on certain topics in the seven categories.

All participants reported some sensory reactions as being too strong. Feeling overwhelmed may have come from the environment where there might be offensive smells, from people who don't respect personal space, or from dealing for a long time with the aversive stimuli. Some participants reported hearing sounds others were unable to hear, overreacting to the touch and feel of different clothing, or feeling overwhelmed by colour and noise in a large store. They reported the inability to filter out sounds, colours, and stimuli made it difficult to focus and concentrate on anything else (Elwin et al., 2013). Participants described compensation strategies in noisy environments as avoiding locations or activities, seeking a calm setting or familiar people, using music with headphones as a calming distraction in a busy and/or noisy place, and creating detailed plans so that activities are structured.

The Elwin et al. (2013) study supports the theory that some autistic symptoms may be related to an individual's attempt to deal with sensory reactions occurring in daily life. To accommodate and improvise is a coping mechanism, and may not be due to inattention, lack of interest, avoidance of social interaction or communication, or to bad behaviour. The sensory reactions may be so distracting and interfering to the individual, that they get in the way of daily life skills and of developing normal cognitive abilities.

The Elwin et al. (2013) study was not large, but content analysis provided an extensive review of both over and under reactions to sensory stimuli of various individuals, with descriptions of their reactions and coping mechanisms. Subcategories such as *Having poor balance*, and *Having poor, exceptional, and varying control and* *coordination of body*, described under the category *Managing sensory/motor stimuli* provided more detailed information about the strength and long term effects from certain stimuli, and the ability of the participant to control or compensate for their reaction. There is always a possibility of interviewer bias with interview methodology, but the same questions were asked of all participants, with the possibility of asking further questions, depending on the initial response. Results should be confirmed with a larger sample. The authors also suggest a new assessment is needed to further explore sensory reactions and their links to additional social and other topics in ASC.

2.32 Young children's individual accounts

Because of a lack of communication skills, interviews with younger ASC children about their sensory experiences have rarely been undertaken. Kirby, Dickie and Baranek (2015) realized a need for more research in this area and undertook a study to first determine the feasibility of interviewing ASC children, and second to understand how the children might share their experiences. Children whose parents had indicated on a previous questionnaire (SEQ; Baranek, 2009 and/or SP; Dunn, 1999) that their child had abnormal sensory sensitivities, were contacted to see if they were interested in participating in the study. During three at-home interviews using video recording, clinical staff interacted with the children, asking simple questions such as *What do you like to do for fun?* to determine if the child would be able to participate, using their clinical impressions of responses.

Twelve children, aged 4 to 13 years, were selected: 10 for video interview sessions and two children were selected just for interviews, as the parent had indicated the child's sensory behaviours could not be recorded at home, but their child could likely participate in an interview. The investigators believed that hearing from the children might provide insights into how to help them deal with their sensory experiences. They experimented with a variety of interview methods, adjusting to each child. They might show the child clips from the interview to solicit greater detail, or use pen and paper if the child seemed to be having trouble verbalizing. Transcripts of the sessions were supplemented with detailed descriptions of the responses, which included gestures and facial expressions, and then coded. The coding of the data began with the question: *How did the children share about their sensory experiences*? (Kirby et al., 2015, p. 318).

A number of findings were reported with three themes emerging from the interviews. The first is that children often described their experiences as likes and dislikes, often generalizing the experience rather than describing exactly why they didn't like something. Second, many children described their sensory experiences as changing from when they were younger, that is, they had "gotten over" their previous dislike. The third theme was that the children often stated that their experiences were like other people's experiences (Kirby et al, 2015).

Some children described how they learned to cope with unpleasant experiences. For example, one child described fireworks as a least favourite thing, but since it's "supposed to be pretty," he liked to watch the fireworks through a window. Another participant chose to watch basketball on TV to avoid the unpleasant sounds of the live game. Sensory experiences were described as causing a physical reaction, often pain as a reaction to touch. Movements might cause dizziness and nausea. Food reactions were described as causing choking, hurting, itchy, or even vomiting reactions. Children commonly talked about their experience as causing a bodily reaction. One child described his experience with loud music as causing his body to shake, and his eyes to blink a lot. As reported by older ASC individuals, children saw their experiences as multisensory. The investigators (Kirby et al., 2015) reported that the children remembered past negative experiences and were afraid they might happen again. Fear and anxiety made the children reluctant to participate in many events and daily activities.

The study was a careful attempt to develop interview techniques that could be used with young children for this and future studies. The authors (Kirby et al., 2015) prompted the children to describe their experiences with storytelling, physically showing what they meant, and comparing their experiences to what they thought was normal. They found that some children had difficulty explaining their experience and at times the interviewers needed to prompt the child with further questions or suggested responses. This was necessary but may have introduced bias. Videos of the interviews complimented the transcription data, and descriptions of behavioural responses that had been gathered, helping to clarify any issues. The study was small and had no comparison group, so the descriptions may not apply only to ASC children. The authors note that children in the study had a broad range of autism severity scores, and that non-verbal children could not be included.

While the results of the study should not be generalized, they add to the number of descriptions of personal experiences and to the potential understanding of how a child with ASC may learn to cope with difficult sensory sensations. The study adds to the evidence confirming the variety, strength, and types of reactions to sensory sensitivities in ASC, as the children's descriptions were similar to adult descriptions of their sensory experiences. The children's answers suggest that change may occur over time in responding to sensory stimuli.

2.33 Adult individual accounts

Forty-five autobiographical texts by individuals with ASC were examined in a qualitative study by Davidson (2010) to gain insights into their daily experiences. After identifying the texts, the author used annotation, coding for themes, and discourse analysis to examine the experience and the accommodation the ASC writers reported making, to manage in mainstream society. While the behaviours may seem odd to a neurotypical individual, the personal accounts reveal that these behaviours help the world make sense, make it less frightening.

A significant theme emerged on the topic of access and accommodation with many writers suggesting the feeling of being excluded came from sensory differences. An individual might feel hyper- and hypo-sensitive, experience a sense as dulled, or distorted, all at the same time. Davidson quotes Shore (2003, p.50) as suggesting the reader imagine “that one’s senses are 1000 times more sensitive than reality.”

Each sense was examined separately for themes (Davidson, 2010). Fluorescent lighting, often used in public spaces, was a common visual challenge. Fluorescent lighting was described by Darius (2002, p.18, cited in Davidson, 2010) as “my brain simply goes into jelly-mode” and another wrote if he were in a setting with muted lighting it made him lose all sense of direction (Gerland, 2003, p. 109, cited in Davidson, 2010).

One individual wrote that his hearing was so sensitive that he could hear the hum of electrical apparatus and that “sounds that other people don’t even notice are disturbing and even painful to me. I have huge problems filtering out what I want to hear” (Darius, 2002, p.12 cited in Davidson, 2010). One of the authors described her experience in school with its high ceilings where she heard a constant murmur that she described as torturous. She wrote “The teacher prattling on was a background to other noises in my ears – the rustle of paper, scraping chairs, coughing, I heard everything. The sounds slid in over each other and merged together” (Gerland 2003, p. 94, cited in Davidson, 2010). Some descriptions added the physical sensation of losing balance and losing a sense of location in space when hearing a sound, revealing that proprioceptive and vestibular senses were included in their experience.

Sensitivity to touch was described by one author as a light touch feeling like “an open wound or getting an electric shock” (Shore 2003, p. 49, cited in Davidson, 2010). Oversensitivity to touch was also described in relation to tasting food, that it is the feel of the food rather than the taste that was behind the author’s strange eating habits (Cowhey, 2005, p. 3, cited in Davidson, 2010). If author Gerland (2003, p 54, cited in Davidson, 2010) touched metal jewellery or metal buttons, she heard a strange sound and reported her stomach turned over. She also was unable to shower as the water dropping on her skin felt painful. Sensitivity to touch was related to types of clothing, belts, ties, and standing on a rug with bare feet.

Sensitivity to smell was noted by author Shore (2003, p. 19, cited in Davidson, 2010) who described perfume as smelling like “taking a deep breath from a Clorox [bleach] bottle.” He wrote that he gets headaches and watering eyes at work when a colleague wearing perfume is in her office on the floor below. As a child Sanders (2004, p. 51, cited in Davidson, 2010) wrote he had difficulties with his sister’s hairspray and electric curlers, which made her hair smell when heated.

ASC individuals reported learning to manage their environments by keeping sensory information to a minimum. Davidson (2010) discusses the differences reported by the ASC authors and asks for respect and space for diversity. Understanding what the differences are between an ASC and a neurotypical individual’s interpretations of sensory events is a first step. The strength of this paper is that it reports experiences with vivid descriptions, so that neurotypical individuals might see “inside” the everyday world of someone whose sensory system is so very different. While the academic, empirical studies confirm that sensory issues do exist, these personal accounts help to somehow "feel" the differences, and to better understand the importance of the issues.

2.34 Individual accounts described as multisensory

Both the children's and adults' responses cited in the previous studies sometimes described their experiences as multisensory. The authors reviewed by Davidson (2010), note that sensory processing is more frequently divided by modality, but their accounts and the ASC children's accounts given by Kirby et al. (2015) implied the senses were experienced in an integrated manner. Personal accounts across a range of ages give support to the idea of a neural network that connects and integrates the senses, an idea portrayed by Porges et al. (2013) as a social engagement system, discussed more completely in section 2.51.

When taken together, the above studies and individual accounts show a picture of daily life for many ASC children, who will have difficulty coping from the moment they awaken in the morning, with sensory overload impacting toileting, dressing, eating breakfast, traveling to school, attempting to pay attention and learn during the school day, playing with other children, and later getting ready for bed and sleeping throughout the night. While children and adolescents report that they do learn to cope with some issues over time, the coping skills generally include avoidance and other changes to behaviours that are often viewed as anti-social.

2.4 Filtered Music Listening Programmes

Filtered music listening programmes have existed since the 1950's and the number of suppliers today is at least 15. Each supplier makes different claims about their programme, but most believe that filtering their selected music in various ways will assist the listener to focus on the speech and language frequency range, to help the listener become accustomed to volume changes and other features of sound, and their programme will help to modify or normalize the listener's response to sound. A list of the programmes is found in Appendix A.

2.41 Use of listening programmes by OTs

Filtered music listening therapies have been adopted by a variety of professionals, particularly occupational therapists (OTs). A survey by Gee, Devine, Werth, and Phan (2013) examined how paediatric OTs in the US are using listening programmes in their practice. The investigators were interested in understanding how and with whom OTs were using the programmes, and what would influence them to choose a programme. Qualifying OTs were recruited through programme equipment suppliers who were asked to invite OTs to participate in the survey study. One thousand paediatric OTs were sent an email, with an overall response rate of 7.4%, with the rate adjusted to 14.7% for those who opened the email. Participants must have worked with children at least 20 hours per week, for the previous six months, and attended a training session by the equipment supplier within the past 10 years. Respondents (N = 74) were from all areas of the US and completed an online survey with 33 questions about their education, experience in OT, and the listening programme they used.

Respondents reported they had used a listening programme in all 12 medical diagnoses listed in the survey from paediatric brain injury, to Down syndrome, to ASC. Deciding to use this type of intervention was subjective and based on client observations (87%). Most individuals who had used the programmes themselves or with their child were referred by other parents (64%) or another OT (39%) and OTs in a private practice setting (57%) were more likely to use them (Gee et al., 2013). Private pay (64%) was the most likely source of financial reimbursement. and was often the only option as the programmes were rarely covered by US health insurance companies.

On a Likert scale of 4 items ranging from *none* to *all of the time*, 39% of respondents perceived the programme they were using to be effective "most…" or "all of the time" (Gee et al., 2013, p. 159). The survey did not ask about success in using the programmes with individual diagnoses, such as ASC. To determine the overall effectiveness of the programmes, participants marked caregiver reports (78%) or subjective observation (74%), and only 49% marked using standardized testing to assess results. Other findings indicated the listening programmes were used with less than half of their caseload (66%), and normally used in addition to other sensory interventions (76%).

The study may not be representative because of a low response rate, survey length, participants recruited through programme suppliers, and other factors. However these programmes continue to be used by OTs in the US and many other countries, and many consider them effective for their clients, so the study was a useful start in pointing out gaps in the field that require further research. The major gaps appear to be no clear standardized assessment(s) to determine who might best respond to this type of programme, and no reliable measure to identify specific abilities and behaviours that might be improved with its usage.

There are many unanswered questions regarding the various listening programmes as little research has been carried out in this field. Individual programmes differ in style of music selected, which may range from pop to classical. Types of filtering may include filtering only auditory peaks or filtering frequency zones, and other modifications may include volume changes and/or surround sound. Protocols may range from 5 days for LLP (Porges et al., 2013) to 20 weeks for TLP (Nwora & Gee, 2009) and daily listening schedules may range from 15 minutes to one hour, all depending on the underlying ideas of the creators. The confusing array of proposed uses and claims of the creators and suppliers make it difficult to identify what aspects of each programme might create change and what types of change should be measured.

Both the Tomatis auditory training method, which was created in the 1950's (www.tomatis.com, 2016, June 15) and the Berard AIT method, which was created in the 1960's (www.drguyberard.com, 2016, June 17), were represented in the Cochrane Review. As many of the other listening programmes are based on the Berard and Tomatis approaches (listed in Appendix A), it will be useful to review their original ideas, to determine if more recent scientific studies have perhaps proven or disproven their original foundations. The ideas for the experimental programme in the present study builds on some of the early ideas of Tomatis, and will also be reviewed. It should be noted that the 15 programmes listed in Appendix A are commercial programmes, and detailed information about their creation is not readily available. For the programme used in this study, TLP Spectrum, a document given to participants in the supplier's training courses was made available and more details are given in the methodology section. The following section reviews studies about the primary theoretical ideas for the field, as the majority of programmes are based on the work of these two researchers.

2.42 Berard AIT

The official website for Berard AIT describes the therapy as "an educational intervention, not to treat or cure medical conditions" (Berard AIT, 2016). Novelty, frequency, and intensity are said to be the necessary components to trigger neural plasticity. Therefore music used should be from the Approved Music List, said to be music including a wide frequency range, having a lively tempo, and consistent volume level. Styles of music listed include "reggae, pop, folk, rock, new age, and jazz."

The website describes the protocol as 30 minute listening sessions twice a day for 10 days. After 5 days of listening, it is possible to have a 1 or 2 day break (www.berardaitwebsite.com, 2016, June 17). The site advises that audio stimulation is never provided by CD's and that MP3 music should not be used, as the music has been condensed by deleting higher and lower frequency ranges. Two specific electronic devices that filter the music, the Audiokinetron or the EarducatorTM, are the only approved devices for the method. Testing is done before the programme session using an audiometer and at mid-point to determine if and how filters will be used with the music. Berard provides specific information on his website about interpreting an audiogram and based on findings, how to then filter auditory peaks, and the process can also be determined by using his Filter Selection Programme (www.drguyberard.com, 2016, June 17).

Audiologists Miller and Lucker (1997) were interviewed about their experiences, by the *American Journal of Audiology* as both had used Berard's AIT method extensively. They pointed out that elements of the Berard AIT method as listed below, were not supported by science at that time, and spoke of some of their concerns.

Berard Ideas Not Supported in Current Scientific Literature

- Peripheral auditory distortion is the cause of hypersensitivity to sound
- Hyperacusis is related to loudness discomfort levels
- Exercising the middle ear muscles is a way to treat auditory distortion
- Audiograms can accurately determine treatment
- Audiogram peaks of 10dB are interpreted as hyperacusis
- Filtering peak frequencies treats the cause of the auditory dysfunction

Both authors agree that use of audiograms is not a valid way to determine treatment. Miller explains that Berard's definition of distortions in hearing did not examine what are considered normal variations, or peaks and valleys, in an audiogram. Berard identified a "peak" as a 5 DB or more frequency change (Miller & Lucker, 1997). Miller adds that other studies by clinical audiologists have reported this is a normal variation, and with some patients who are difficult to test, such as ASC children, peaks of 10 dB or more are not unusual. Miller explains that children with autism often show these variations, but then on retest, they are often not present. Both Miller and Lucker agree that the underlying rationale for treatment is erroneous. Miller argues that AIT is unproven and not an acceptable treatment for autism, while Lucker offers a more cautious view.

Lucker points out while some of the original theories have not held up to current science, there may be other mechanisms at work. He notes that AIT is an auditory training method and therefore should improve auditory behaviours, not necessarily all the other deficits promoted on the website (Miller & Lucker, 1997). Lucker suggests another possible mechanism, that because of the nature of the modulations and their unpredictable changes to the music in the programme, listening requires more attention and more processing of the sound, and this may lead to improvement in listening skills.

Lucker had been involved in many investigations with the programme, and had repored that the thresholds Berard measured in the audiograms had never been a positive indication of change. Changes instead had been noted in listening tasks, competing sentences, memory, and following directions. Lucker pointed out that the Berard AIT studies were small, but consistent changes were noted (Miller & Lucker, 1997). As there did seem to be an effect for some children and few interventions exist, Lucker suggested that rather than abandoning the programme, future studies should determine which individuals might benefit most from the training.

This critique of the Berard AIT method by Miller and Lucker was published nearly 20 years ago. Its main strength is the respondents were both audiologists who had used the method extensively, and were knowledgeable about the physiology of hearing and sound processing. Lucker's view remains valid, that there appears to be an effect for some children, and as few proven interventions exist to improve auditory behaviours, more research should be done in this field.

A more recent study by Gravel et al. (2006) was conducted to determine if peripheral hearing, meaning hearing in the outer and middle ear and cochlea, was different in children with ASC as compared to neurotypical children. They reported that Berard believed his AIT method, when used to alleviate hypersensitivity to sound, improved peripheral hearing. Participants included 37 children with ASC and 37 children who were neurotypical and matched to age. Two tests, the first using a standard clinical audiometer and the second using a computer controlled behavioural audiometric test that controlled for possible examiner bias, were administered. Possible examiner bias using a standard clinical audiometer had been a criticism of previous studies.

The investigators (Gravel et al., 2006) found there were no differences between the ASC and neurotypical groups on any measures, including acoustic middle ear muscle reflexes, indicating that peripheral hearing was intact. Children with ASC did not show greater hypersensitivity to sound, and did not exhibit abnormal peaks and valleys in audiometric testing more than the neurotypical children, both part of Berard's assumptions and method for treatment. Even the subgroup of ASC children whose parents reported hypersensitive hearing issues were no different in any measures than other ASC children.

Gravel et al., (2006) state that efficacy of the Berard AIT method has no published evidence, and that Berard's explanation of sound sensitivity and the audiometric patterns on which the intervention is based, have not been shown to be valid. The results confirm the views presented earlier by Miller and Lucker in 1999.

The Gravel study was rigorous in careful diagnosis of ASC for all participants, testing hearing at baseline, exclusion requirements, and in attempting to address possible confounding issues noted in previous reports. The research audiologists used the two types of testing noted above to diminish examiner bias, and extensive analyses were performed to be certain there was nothing that should be flagged as atypical. Only children at the high end of the spectrum were tested, but the authors note that hyperacusis and other sound dysfunction are often reported across the spectrum.

The study addresses several of Berard's ideas related to his AIT programme including the belief that middle ear muscle function and peripheral hearing are different in ASC children. If efficacy of the programme is confirmed in future studies, the creators would need to provide a different theoretical basis for filtering peaks and valleys based on middle ear muscle function as the basis for change. As Lucker proposed in 1999, there may be other reasons that change has been reported.

2.43 The Tomatis Method

The official website for the Tomatis method states that the method stimulates the brain so that the ear learns to listen (www.tomatis.com,"The Method", 2016, June 15). The author of the site claims that the programme may be applied to a variety of issues ranging from learning difficulties and language disorders, to improvement of the voice and of musicality, preparation for childbirth, and integration of foreign languages." An individual therapist may only use the programme with his or her specialty, so the website has been used as a reference to illustrate the "official" description of the method.

One of the ten areas of application listed is Pervasive Developmental Disorder, which is said to also include Aspergers syndrome. However the author of the site notes; "Numerous approaches are possible to help people presenting with these disorders. The Method is not exclusive in this regard." (Tomatis "Areas of Application," 2016). The site's author also states that while the method does not eliminate the issues of learning and/or language disorders, it does help the person manage them, although "managing" is not defined.

The method as it is currently implemented, is briefly described as starting with an interview to determine what aspects the individual would like to improve. The sessions begin with a passive listening phase, and may take place in a clinic or at home (Tomatis Method, "Following listening sessions," 2016). The length and number of sessions depends on the individual's reported difficulties, but sessions are usually two 13-day periods of two hours of daily listening. An "active phase" then may be proposed, when the individual reads or repeats words and phrases and he/she hears their own voice through the Tomatis headphone listening device, which is said to correct the way you hear your own voice. When listening sessions are completed, an exit assessment is given to measure progress, and to determine if further listening is recommended. No details are given on the type of measurement used and this may differ somewhat between types of therapists.

Andersen (2011), a Danish researcher in acoustics at Aalborg University, investigated the Tomatis method and asked if there was any evidence that listening training could improve hearing. She noted that listening training methods have often been created from a creator's experience and observations rather than from scientific studies. Anderson then performed a critical literature review to explore if the basic ideas of Tomatis hold up to current science.

Thompson and Andrews (2000) described how the Tomatis method evolved from his work with hearing loss in singers and ammunition factory workers. The first concept was called the Tomatis effect and was confirmed in 1957 at the Sorbonne in Paris (Tomatis, 1991, p.66). The concept stated "A person can only reproduce vocally what he is capable of hearing" (Thompson & Andrews, 2000, p. 176). Tomatis believed that re-educating the ear to restore missing frequencies would immediately affect voice quality. Tomatis also believed that hearing your own voice, when it had been improved by his method, would instigate change that would be maintained as the ear became accustomed to clearly hearing the changes. The authors explain that these concepts came from Tomatis observing audiograms and spectrographs of the two cited groups, singers and factory workers, and led him to develop the device he called the Electronic Ear (EE). Thompson and Andrews explained that the discoveries he made drove the development of the device and Dr. Tomatis "received seven U.S. patents for components of the EE" (p. 176). Because the device was not portable, listening was done in a clinic. Easily portable listening devices have changed the way the method is normally delivered today and changes in technology helped to spur the growth of the field of auditory stimulation.

In addition to vocal training Tomatis also taught that right ear dominance was preferred as a more direct connection to processing speech, and that dominance could and should be changed to have a leading right ear (Thompson & Andrews, 2000). He believed the middle ear muscle could be strengthened to operate more efficiently, and that bone conduction was important for sound moving to the inner ear. His Electronic Ear could delay the timing of bone conducted sound as compared to air conducted sound, which he believed supported a faster response to incoming sound.

According to Andersen (2011), some elements cited by Tomatis as a reason for his approach have been scientifically supported, while she was unable to find support in current science for others. The items listed in the two categories do not represent a complete list of Tomatis's ideas.

Tomatis Ideas Not Supported in Current Scientific Literature

- It is possible to change ear dominance
- Changing ear dominance will create change in voice characteristics (such as monotone)
- Middle ear muscles can be strengthened, which improves focused listening and paying attention
- The delay between bone and air conducted sound causes a difference in speed of sound reaching the brain

Tomatis Ideas Supported in Current Scientific Literature

- Right ear dominance is an advantage for speech processing (Kimura, 2011)
- Vocal output can be corrected by auditory feedback (Pantev et al., 1999; Menning et al., 2000; Tourville et al., 2008)
- The auditory stimulation in the method promotes nerve growth (Pantev et al., 1999; Menning et al., 2000)

As the majority of music used in the Tomatis method is Mozart, Andersen (2011) first looked at support for the choice of music.

In the original study of what became known as "The Mozart Effect," Rauscher, Shaw, and Ky, (1995) asked 79 students to listen to either 10 minutes of a Mozart sonata (KV448), a relaxation tape, or silence for five consecutive days. The data showed that on spatial-temporal reasoning tests, the Mozart group scored better than either of the other groups, showing a significant day effect of $p < .001$ after day 2, or 62% for the Mozart group, 11% for the relaxation group, and 14% for the silence group and a significant day by condition interaction of $p < .01$. Days 3 to 5 again showed highest scores for the Mozart group but did not differ significantly as compared to the silence group. The relaxation group scores remained below the other two groups. The effect lasted only 10-15 minutes, while participants were engaged in the spatial task.

The study grabbed headlines in the media and became known as the "Mozart Effect". Schellenberg (2001) wrote that in May 2000, 20 tests of the Mozart Effect had been published but less than half were able to replicate the effect. Schellenberg suggested the findings should be interpreted based on studies showing that positive mood influences cognitive tasks, and that arousal from enjoying the music as compared to sitting in silence likely created the effect.

Other studies have used Mozart to test different effects that might be measured from listening. One study exposed 12 healthy preterm infants in hospital to Mozart, or Bach (from "Baby Bach" and "Baby Mozart", Baby smart, Nir Zvi, Israel), or no listening for 40 minutes at the same time daily for three days to compare the effects and determine if the music would significantly lower Resting Energy Expenditure (REE). REE is a measure of breathing, of O_2 intake and CO_2 production, a measure that is safe for infants in an incubator, and which does not interfere with their care. A lower rate is considered to be a more relaxed state. The investigators (Keidar et al., 2014) found a significant reduction in REE when measured after 30 minutes of listening to Mozart's music (p = .041), but not to the music of Bach (p = .59). The authors suggest that the music of Bach is more complex, and may not be as soothing to preterm infants, but understanding an exact mechanism would require further research.

While Anderson did not find support for Tomatis's idea of changing ear dominance and his proposed effect of change in voice characteristics, there is evidence that right ear dominance does provide an advantage for speech processing. Kimura (2011) described how she first tested patients with left temporal lobe damage in 1961, while working on a Master's thesis, while attempting to define left and right temporal lobe function. Patients listened to recorded words and Kimura reported that more words arrived correctly through a patient's right ear than their left. She then tested right-handed normal subjects and found they also showed a significant right-ear advantage. A later test was done with environmental sounds but these did not show a right ear advantage. The effect of right ear dominance appeared to be limited to speech.

Since the early research by Tomatis, it is now accepted that the brain changes with exposure to sound. Thompson and Andrews (2000) wrote that Tomatis believed his method promoted nerve growth by auditory stimulation of the nervous system connections with the ear. It is now known that sensory stimulation from experience does cause the brain to change, and this continues to occur throughout the lifespan. There is supporting evidence that brain plasticity occurs from auditory stimulation and can be measured in the auditory frequency map when listening to filtered music. Normal hearing for low to high sounds is represented by a frequency range in the human auditory cortex from 20 to 20,000 Hz, and the range normally decreases with age. The following two studies were created to determine if training by listening to sound would cause change in the frequency map in the brain.

The first study to measure brain change with auditory stimulation was undertaken by Pantev, Wollbrink, Roberts, Engelien and Lutkenhoner (1999), and ten subjects with normal hearing, seven males and three females, were asked to listen to their favourite music. The investigators had removed a narrow frequency band in each individual's chosen music, using filters around 1 kHz, (between 0.7 and 1.3 kHz) with a control stimulus of noise bursts present at around 0.5 kHz, one octave apart. The goal was to determine if the auditory frequency map in the brain would change in response to listening to the filtered music over a short time period. The subjects listened for three hours per day, on three consecutive days and were allowed to read or use the Internet while listening. Before listening and immediately after the end of the three hours, the subjects were tested using magnetoencephalographic (MEG) measures, which record the magnetic field related to electrical neural activity at the scalp. MEG measures were averaged daily for the auditory evoked field amplitudes, for each subject for three days.

Data showed the diminished area that had been filtered at 1 kHz returned to the baseline measure each day within the 24 hour period between listening sessions. Analysis of variance (ANOVA) was used to evaluate the MEG data taken before and after listening for main effects for days 1-3 and to examine interactions of test and control stimuli. Investigators found the neural representation in the frequency map for the area that had been filtered was about 10% smaller than for the control stimulus after 3 days and data from each day showed there was a cumulative effect. Analysis using paired *t*-tests showed a significant effect for before and after filtered music listening (p = .009). There was also a significant effect for the interaction for exposure over three days, before and after, (p = 0.043), but no significant interactions for exposure or of main effects for the control stimulus.

The authors (Pantev et al., 1999) suggest that rapid changes can occur in the adult human auditory cortex in response to changes in auditory stimulation. The study was carefully designed and special care was taken to ensure head position was constant and exact body position was maintained for all tests. The study provides evidence for plasticity of the auditory cortex, showing change to the frequency map during stimulation both daily and for an accumulated effect over time. After a three hour period of auditory stimulation, recovery would occur and return to the baseline measure before the start of the next daily session, another example of plasticity. The study is also relevant to a structured listening programme as it demonstrates plasticity occurred listening to filtered music and that protocols, particularly length of listening time, are important for lasting change.

Another study examined the sound frequency map in the brain, to see if training would improve the ability to distinguish pitch changes, represented by small changes in the frequency map. Menning, Roberts, and Pantev (2000) paid ten volunteers ages 20 to 32, to spend 1.5 hours per day for 15 sessions over a three week period, to see if change in the auditory cortex would occur. The investigators trained the subjects to discriminate pure tone bursts of 1000 Hz with shifts to 1050, 1010 and finally 1005 Hz, testing before and after the training. The subjects pressed a left or right button indicating if the pitch was the same or deviant and if correct, a green square appeared on a computer screen, if in error, a red square appeared. At least 5 correct tones were given at the beginning of the discrimination training session before a change was presented, which then followed a random pattern. The investigators found that discrimination improved quickly the first week, with small but constant improvements the following two weeks.

MEG measurements, showing auditory discrimination processing in the brain, were taken at baseline (twice during three weeks prior to the first training), at one and a half weeks, three weeks, and at a three week follow up. Care was taken to ensure head and body positions were stable and an animated video was played to focus the visual attention of the subjects, who were asked to remain awake but relaxed. Tone bursts were given during the MEG measurements of the three frequency shifts of 1050, 1010, and 1005 Hz used for the training exercise. Data for each measurement session were averaged. A repeated measures ANOVA showed a significant effect between baseline and middle training phase ($p = 0.018$), and middle and post training ($p = 0.0138$). Change was greatest in the first week, detectable in all subjects, with smaller gains the second week, with gains detectable in 72% of the tests. At the smallest frequency difference or pitch change of 1005 Hz, change was detectable in just 4% of the tests (Menning et al., 2000). Change in the frequency maps was suggested to occur because of practice or repetition, indicating experience and learning. The threshold limit for change appeared to be stable by the third week, then decreased when the subjects were tested three weeks after the training had ended. Main effects due to training phase (p = .0116) were found. Post hoc tests (Bonferroni-Dunn) showed significance between baseline and the middle phase of training (p = .007), and middle phase to post training measures (p = .005). No other contrasts were significant.

Menning et al., (2000) concluded the brain's sound frequency map can be modified by auditory input and that changes depend on intensity, duration, and frequency of listening. The study adds to the evidence for brain plasticity in the auditory cortex, showing that listening to sound can create measurable change in the auditory frequency map. Both studies (Pantev et al., 1999 & Menning et al., 2000) provide evidence that normal hearing may be disrupted by small changes in a sound source, and the effect can be seen in the frequency map in testing. The two studies together provide support for the possibility that auditory listening training, in a structured programme with specific repeated sound input, may improve frequency discrimination, and modify gaps or reductions in the brain's auditory frequency map.

2.44 Porges' Listening Project Protocol

The Listening Project Protocol, LPP, is the name given to a filtered music listening programme developed by Porges (2014) for his research. It is not a clinically available intervention, and differs from commercial listening programmes in both method and theory. However, Porges' social engagement theory and his research using LPP provide a helpful understanding of how a filtered music listening programme may promote change, particularly for children diagnosed with ASC.

Porges' main body of work was his Polyvagal theory, (Porges & Fruman, 2011) which he described as a biobehavioural model to explain the development of a system that has learned to respond to a changing environment. The senses, via the nervous system, act as the receptor for environmental threats and the body may respond by total withdrawal, fight or flight, or by engaging socially.

Porges' theory of social engagement (2013), which emerged from his polyvagal theory, described a system that receives information through the senses and works at a subconscious level to keep an individual safe. The sensory network supporting social engagement involves five nerves in the central nervous system: V, VII, IX, X and XI, regulating the face, head, and neck, with the vagus nerve (X) regulating heart rate and breathing.

Gillig and Sanders (2010a) provided a review of the anatomy of these nerves and how they relate to various disorders in psychiatry. Cranial nerve V, the trigeminal nerve, innervates sensations in the face and head, feeling on the tongue, and muscles for chewing. It also innervates the tensor muscle in the ear, which allows the tympanic membrane to dampen sound vibration in order to reduce the perceived volume. The facial nerve (VII), innervates the muscles of facial expression, sensation in the external ear, and with the trigeminal nerve, is involved in taste. Gillig and Sanders point out that the facial nerve also innervates the stapedius muscle of the ear, which dampens movement of the ossicle in order to lower sound volume and to protect the inner ear from damage. Both nerves V and VII play a major role in sensitivity to sound by adjusting volume in the ear.

A second article by Gillig and Sanders (2010b) describes cranial nerves IX, X, and XI, also part of Porges' (2013) engagement system. The glossopharyngeal nerve IX, the vagus nerve X, and the spinal accessory nerve, XI, all have both sensory and motor divisions. The glossopharyngeal nerve has sensory connections to the pharynx, middle ear, and part of the tongue with motor connections to swallowing. A communicating nerve connects the glossopharyngeal nerve to the vagus nerve. Motor connections of the vagus nerve link muscles of the pharynx and the larynx, which makes pitch adjustments in the voice. Pain and a sensation of fullness are both functions of the vagus nerve. The vagus controls heart rate and breathing, needed to engage and disengage fight or flight behaviours. It also regulates taste and sensation from the external ear via the auricular branch. Cranial nerve XI, the spinal accessory nerve, innervates muscles that move the head and neck.

To illustrate, when an individual hears a human voice, sound enters the ear and the middle ear muscles must be able to focus on a voice above background noise. The middle ear muscles are connected to muscles that open the eyelid, which allows an individual to look at the person speaking. Facial muscles may be used to show expression and communicate emotion (such as smiles or frowns), neck muscles may turn the head towards the person speaking, and laryngeal and pharyngeal muscles help to enable speaking. Together these cranial nerves make up a connected system that supports engaging socially with others (Porges et al., 2013).

Porges's first listening project (2001) was an effort to access this system, by providing auditory stimulation through the ear. His idea was to determine if by removing the lower frequencies with audio filtering in children's music that had vocals, listening might help the child to focus on the higher frequency range of the human voice. If his theory about the social engagement network was correct, he predicted improvement would affect eye gaze, facial expression, speech, and the ability to regulate behaviour. As all of these are commonly reported as dysfunctional in autism, he selected ASC children as participants for his studies.

The first of three studies using his LPP tested the programme on 65 children ages 3 to 5 years diagnosed with ASC in a double-blind RCT (Porges, 2001). He claimed that most children experienced improvements in communication and social behaviour, and the improvements lasted when tested three months later. While the study is mentioned in his published papers as a test of his theory, a separate study on his original Listening Project was never published.

A second study (Porges et al., 2013) using the LPP evaluated two common elements of ASC, the inability to manage change and difficulties in auditory processing, which can be observed in abnormal behaviours and language skills. Participants ages 6 to 21 were recruited for the ASC group (N = 78) and for the control group (N = 68). Baseline measures were taken of heart rate variability using respiratory sinus arrhythmia (RSA) to measure improvements in the ability to manage behaviour. ASC participants had significantly lower RSA ($p < .001$) at baseline than the control group. The ASC group was measured for RSA while taking the SCAN Test for Auditory Processing Disorder (Keith, 1986, 2000) and a repeated measures ANOVA revealed a significant interaction of group x condition. Two subtests were selected to measure improvements in the ability to understand speech in background noise and the ASC group scores were significantly poorer for Filtered Words ($p < .001$) and for Competing Words ($p < .001$).

A subset of ASC participants took part in a second study one week after baseline tests and were then assessed following the LLP protocol of one hour daily listening sessions for five days. Results indicated that both Filtered Words and Competing Words in the SCAN test showed significant improvement ($p = .001$) and RSA improvement was also significant ($p = .007$) as compared to baseline. Porges suggested that when the social engagement system is compromised, specific behaviours emerge. Because the system is integrated, it may be possible to use sound as a way to access the system through the ear, and improve its function.

A third study using the LPP (Porges et al., 2014) documented the effect of the programme on auditory hypersensitivities and was described earlier in section 1.6, as results showed a difference in filtered and unfiltered music listening. Change was measured in several areas, but a second trial showed that a reduction in sound sensitivity (p = .040) and emotional control (p = .019) were the two improvements that could be attributed to LPP, the filtered music programme. The other improvements were also evident with unfiltered music listening. The study underscores the need to examine the difference in results between listening to filtered and unfiltered music and this was incorporated into the present study design.

2.5 Experimental Programme - TLP Spectrum

The Listening Program (TLP) Spectrum is the name of the third edition in a series of listening training programmes developed by Advanced Brain Technologies (ABT). ABT have recorded their own music and produced their own audio recordings for their programmes. They selected instrumental music composed by Mozart as used by Tomatis, but added similar music composed by Haydn, Vivaldi, and Danzi, stating it was to provide more variety for the listener (ABT, TLP Spectrum, 2016).

The creators of TLP followed the Tomatis views on filtering, isolating three zones defined by specific frequency ranges, and list a fourth zone said to contain the full range of frequencies (Appendix B). As described earlier in this paper, Sollier (2005, p. 197) wrote that as Tomatis changed the frequency bands for the individuals who were listening to Mozart with his Electronic Ear, he had observed changes in his patients. Frequencies that appeared to affect the body were from 125 Hz to 1,000 Hz, frequencies that appeared to affect language/communication were from 1,000 to 2,000 Hz, and frequencies that appeared to affect an individual's creativity were from 2,000 Hz and beyond. While the observations Tomatis reported making in his clinic have not been proven, the creators of TLP believe it is important to stimulate all the frequency bands throughout the structured programme.

The TLP Spectrum Provider Reference (2012) is not a public document but is provided to professionals who take the company's training to become certified to oversee the listening programmes, where they are taught about auditory sensitivities, how the programme was developed, who might benefit from the programme, how to start a sensitive child with listening through headphones, and so forth. The reference document was provided on request to the investigator. The TLP document (Appendix B) explains the Spectrum edition of the programme was created specifically for listeners with greater sensory sensitivities, particularly children with autism or individuals with brain injury.

Changes were made from their previous edition, called TLP Level One, based on observations and feedback provided by therapists who had worked with sensitive individuals using the earlier edition. A major change was to incorporate filtered music emphasizing low frequency sounds into the second daily listening segment, to always provide a greater sense of calm. The stated goal of the programme was to help the listener develop a healthy relationship with sound. While not specifically stated in the reference document, a healthy relationship might include overcoming hyper- and/or hypo-sensitivity, and improving auditory filtering. The Spectrum programme presents the Tomatis ideas for filtering according to frequency zones and the following additional ideas described in ABT's reference document, are listed here by the researcher.

It should be noted that a preliminary search was undertaken to determine if there might be any support in the academic literature for these ideas. This was a limited search untaken using the language found in the reference document, rather than a systematic review of all available evidence. This type of search may have limited the number of documents found and may have led to publication bias.

2.46 TLP Spectrum Ideas Supported in Current Scientific Literature

- Hypersensitivity may be an emotional response to sound (Gravel et al., 2006; Lucker, 2013)
- Low frequency sounds add to a sense of calm (Liu et al., 2003)
- Spatial Surround can help a listener develop awareness of his/her spatial environment by training sound localization (Wright & Fitzgerald, 2001)
- Improved timing is possible with listening (Honing & Ladinig, 2009)

A brief search of the literature looked for studies about hypersensitivity, to determine if any studies supported it as an emotional response to sound. As hypersensitivity is commonly reported by parents of ASC children, researchers have attempted to find a physiological difference that might indicate hyperacusis. One study was by Gravel et al., (2006), and was described in more detail earlier (p. 55). The investigators tested thresholds for loudness as a part of numerous audiometric tests of a group of 37 ASC children and 37 neurotypical children, to determine if there were any differences between the two groups. No detectable differences were found between the groups, even the subset of children who were reported by their parents to have sound sensitivities.

Lucker (2013), an audiologist, found similar results and proposed that hypersensitivity may be an emotional reaction to sound. He conducted a retrospective review of records identified from his clinic files over a 5 year period, of 50 ASC children and 150 neurotypical children. Loudness tolerance had been assessed for all the children who were reported as having auditory hypersensitivity problems by a parent or professional. Findings from the data indicated the percentage of ASC children who were unable to tolerate loud sounds was much smaller than expected. Only one child, in the ASC group, was unable to tolerate sounds at 90 dB. The number of children unable to tolerate loud noise grew with an increase in sound level. Above 110 dB, a very loud level, there was a significant difference between groups, and more ASC children (14.5%) had tolerance problems at this level as compared to the non-ASC group (8%). There were no gender or age differences.

Based on these findings, Lucker (2013) supports the conclusion that rather than an auditory-based reaction, intolerance to sound may be due to an emotional reaction. Anecdotal reports of ASC children who react strongly to a sound under one condition, and tolerate the same sound under another condition, supports this conclusion. Lucker reports that desensitization has helped some children to adjust. He also mentions that listening programmes have been used to help reduce sound sensitivities, but states that limited research has been done for hypersensitivity, and additional carefully controlled studies are needed.

The discomfort expressed by some ASC children in reaction to sound may not be measurable by the audiological test used by Lucker et al. (2013) or by Gravel et al. (2006). Lucker's view, that the discomfort reported is an emotional reaction, is not based on direct evidence. New studies using different measures may show that hyperacusis is based on a different auditory or sensory system dysfunction. One of these was used in a recent study that assessed hyperacusis using a measurement of the medial olivocochlear (MOC) reflex (Wilson et al., 2017). The authors report they found a significant correlation between hyperacusis symptoms and MOC scores. In children with severe hyperacusis, the MOC reflexes "were approximately twice as strong" as compared to neurotypical children and to those with "not-severe hyperacusis" (p. 1164).

Another possible neurophysiological explanation relates to the middle ear muscle, whose function is described in the social engagement theory of Porges et al. (2014) cited earlier. Porges proposed that the inability to tolerate loud sounds is related to the neural regulation of the middle ear muscle, which is not currently measured. In order to assess the function, Porges and Lewis (patent pending) have developed what he described as “a middle ear sound absorption system (MESAS) to measure middle ear transfer function” (p. 9).

Understanding synaesthesia, defined as one sense triggering the experience of a different sense at the same time, may also provide a different explanation for hyperacusis. Rates of synaesthesia were found to be three times as high in the ASC population (Baron-Cohen et al., 2013), and personal reports of this experience are given later as individuals describe their experiences with sensory overload as more than one sense being triggered at the same time. Baron-Cohen reported that both those diagnosed with synaesthesia and autism, have shown an increase in brain connectivity. Further research into the possible origins of synaesthesia, auditory dysfunction of MOC reflexes (Wilson et al., 2017) and the middle ear transfer function (Porges et al., 2014) may provide additional insights and a different valid measure for any underlying physiological cause of an ASC child’s abnormal reaction to sound.

The supplier also claims that the experimental programme uses low frequency sounds in specific modules because they are calming. Various studies examining how music might affect mood have developed ways to label emotions, but have not always been consistent in their choice of descriptive labels. Categorising music based on emotional content is complex and many factors play a role in an individual’s response to emotion. The discussion starts, according to Beveridge and Knox (2012) with the following question. Does the music induce an emotional response in a listener or does the music express an emotional response, which is then perceived by a listener? The response to the first question is more difficult to predict as it relies on personal associations. In many situations, this personal association and emotional connection with the music has been shown to be the most effective in reducing anxiety and distress. For example, the role of emotional connection with music has led to the creation of playlists for seniors with dementia, by selecting music from a specific time period and finding selections that have individual meaning (Garrido et al., 2017).

Beveridge and Knox (2012) say the answer to the second question is more often used in research, because there is more common agreement by listeners. Emotional perception can be examined by analysing acoustical and structural features and their interaction in selected music. The Beveridge and Knox study was designed as a first step in creating a classification system for the broad range of styles and genres found in western popular music that could reliably distinguish emotional categories.

Similar research was undertaken by Liu, Liu and Xhang (2003) for the western classical music genre. The authors developed a framework that could be used by listeners, an individual could more easily find the type of music they desired. Their stated goal was to develop a mood detection algorithm that would analyse sound data from a piece of classical music.

For their study, Liu, et al., (2003) examined a model created by Thayer, which had been used in the late 1990's, and proposed that mood came from two factors: either stress as happy or anxious, or energy as calm or energetic. Factors in music were identified as intensity corresponding to energy, and timbre and rhythm as corresponding to stress.

Two experiments were designed to track mood in 250 pieces of classical music that used different orchestration styles such as orchestra, piano, choir, and string quartet. Three music experts selected and annotated 200 20-second representative music clips, for each of four moods: contentment, depression, exuberance, and anxiety. Based on the music experts' initial classifications and subsequent testing, the first process classified the selection as group one (Stress) or two (Energy) based on intensity, then using timbre and rhythm to further classify the selection as contentment, depression, exuberance, or anxious (Liu et al., 2003). Music in the contentment/depression group was judged to match data showing lower energy, lower timbre, and slower rhythm with contentment having a brighter and more harmonic timbre than depression. The exuberance and anxiety group had greater energy, higher timbre, and strong, steady, and fast rhythm.

The mood detection system (Liu et al., 2003) was tested in two experiments to ensure that the categories and descriptions were accurate. The system was compared to the music experts' categories and the overall accuracy for the system was reported as 86.3%. The approach was shown to perform better than previous systems and to provide satisfactory results. The system was also tested on several complete pieces of classical music and was deemed satisfactory in detecting the mood in larger segments. Given that descriptions of mood in music are highly subjective, the study provides precise language that is valuable for research. The value for the present study was the creation of definitions that are specific to classical music, were tested for various moods, and included features of each mood. The findings support the idea that low frequency sound is a feature of calming music,, as stated in the Provider Reference Document (Appendix B) for the experimental programme.

The supplier also claims to provide training to improve localizing sound, so a brief search was conducted to look for studies that might show if the ability to locate sound could be trained with specialized listening. Locating a sound source depends on differences between the two ears in the sound's arrival time and volume level. Wright and Fitzgerald (2001) created two studies to examine how training might affect the ability to locate a sound source. Sixteen participants were in the trained group and 16 in the control group, all with normal hearing. Sounds were digitally produced tones, one to each ear, delivered through headphones. One group had trained with headphones for one hour daily for nine days, pressing a computer key when hearing the sound in a different location. Training included both volume level and timing differences. Two groups of listeners were asked to focus on interaural level differences (ILD) or interaural timing differences (ITD), which were presented through headphones. They were asked to mark the location where they perceived the sound was located, on a diagram of a head, and describe how the lateral position of the sound changed. Each participant in the training groups was given an hour of practice over 9 or 10 days, with pre and post testing.

There was a significant difference for the group of trained listeners in performance ($p < .0001$) of interaural level differences, but not for the listeners trained with interaural time differences. Data showed it took longer to learn level differences than time differences, but learning did occur for both types of sound cues. There was a significant change in performance for the trained listeners as a group ($p < .001$), as compared to the control group (Wright & Fitzgerald, 2001). One month after the training, five listeners in the ILD trained group were tested again to see if learning persisted, but there was no significance in main effect or interaction.

This was a complex study with many suggestions for the variations in learning time and results (Wright & Fitzgerald, 2001), such as one type of learning may have been easier as compared to the other, or that participants were already accustomed to focusing on the timing cues, but had to learn how to focus on the level cues. The authors conclude that plasticity exists in processing cues that improve the ability to locate sound. Its main relevance to the present study is that it did show preliminary evidence that listening practice can improve discrimination of volume level and time level cue types, which are both necessary localization skills.

Localizing a sound source is important for safety, as it improves a listener's understanding of where the sound is located in time and space. It also indicates where an individual should focus visual attention, used to confirm the location of the sound source. The study provides preliminary support for the idea that spatial sound training may help a listener develop awareness of his spatial environment. It is relevant to the present study as the experimental programme contains a training section to improve sound location (ABT, "TLP Spectrum," 2012).

Timing is also expected to improve with listening training in the experimental programme. A brief search revealed a study by Honing and Ladinig (2009), who examined the expertise hypothesis, that proposed musical abilities were developed solely by training, and the exposure hypothesis, that proposed musical abilities could also be developed by listening to music. In their study, expressive timing was examined to see if daily music listening by non-musicians might influence their timing judgments. The investigators wondered if the non-musicians would be able do a comparison task about timing as well as trained musicians. They created an Internet-based listening task to compare timing in classical, jazz, and rock music, and recruited 208 participants, aged 12 to 63, with various musical backgrounds. Categories of musical expertise showed 34% had little or no expertise, 29% could be called musical experts (more than 8 years formal training beginning before age 9) and 37% could be labelled semi-musicians.

Musical preferences were indicated by main exposure time as follows: 39% mentioned classical, 27% jazz, and 24% rock music.

Two similar instrumental pieces were selected from commercial recordings and in one piece, software changed the tempo. Participants were told about the change and asked to listen for the timing rather than the quality of the recordings, which might have varied on different computers. They were then asked to select the piece that was the real recording, not the piece that had altered timing. Participants who did not listen to the complete fragment of music or who did not complete the experiment were eliminated. Honing and Ladinig (2009) reported that 60% of the remaining participants were able to correctly identify the real performance as compared to the piece with altered timing.

The authors (Honing & Ladinig, 2009) then analysed the effects of both expertise and exposure between the three listener groups and were able to conclude that each group was able to distinguish the real recording from the one that had the timing changed, and that significance was above chance level ($p < .05$). They concluded that expertise in timing was related to exposure to the musical style by listening, rather than a level of musical expertise from training. Many other studies focus on the results of formal music training, but this study revealed that some musical capabilities, such as timing, may be acquired by exposure through listening. The study was well designed and controlled for musical expertise, style of music, expertise related to genre, and focus of the listener on the recording. Results provide support for the experimental programme creator's idea that improvement in timing is possible with listening.

2.6 Possible Mechanisms for Change in Listening Programmes

Some of the ideas the creators of the first filtered music listening programmes proposed 50 years ago as the supporting science behind their therapies have not stood the test of time. These include the idea that auditory distortions in hearing can be defined by peaks and valleys seen in an individual's audiogram, and that filtering based on the peaks and valleys can be used to treat the problem (Miller & Lucker, 1997; Gravel et al., 2006; Andersen, 2011). Some of the original ideas have been proven, such as brain plasticity, the ability of the brain to grow new cells and form new connections. Individual studies show plasticity applies to frequency gaps being reduced and then restored in the auditory cortex in sound frequency maps (Pantev et al., 1999), learning to detect pitch changes (Menning et al., 2000); and that it is possible by repeated listening, to improve timing (Honing & Ladinig, 2009) and sound localization ability (Wright & Fitzgerald, 2001).

Another idea promoted in early listening therapies that has not been proven is that the middle ear muscle is dysfunctional in ASC children and is strengthened by exercise, which was said to be provided by filtered music listening programmes. In a series of tests of 40 ASC children matched to a group of neurotypical children, Gravel et al., (2006), whose study was cited in detail earlier, found no differences in audiologic function, including a test for acoustic middle ear muscle reflexes. Porges et al. (2013) believed that it was the neural regulation of the middle ear muscles that was dysfunctional rather than muscle strength, and this was a function that could be measured and improved. He wrote that he and a colleague had developed a new device that would measure this transfer function, and that it was being tested. If his measurement device proves to be effective, it may provide evidence for a possible mechanism for change, the neural regulation of the middle ear muscle.

Dunn's conceptual model (1997), described in more detail in section 2.1, was created as a way to identify behaviours associated with sensory difficulties, in order to serve as a guide in creating effective therapies. The model incorporates The Sensory Profile (SP; Dunn 1999), created to identify behaviours associated with each of the senses and to rate their severity. The profile provided a way to evaluate a child's threshold of tolerating incoming sensory information by observing their response. Dunn's concept for treatment may also relate to filtered music listening programmes, as the creators describe adding extra auditory challenges to pleasant music in a structured programme. It may be that with the appropriate protocols, sensory thresholds that have triggered an abnormal reaction could lessen, and become more typical over time.

2.5 Studies using The Listening Programme

The experimental programme website lists a number of exploratory studies undertaken in schools, one study of ASC children measuring auditory filtering skills, and a number of case studies for autism which are located in the science/research section of the ABT website (www.advancedbrain.com, "Research," 2017), however most of the studies are not peer reviewed. Following are five case studies that have appeared in academic or professional journals and one quantitative summary of nine studies using effect size as a common measure.

Occupational therapists Nwora and Gee (2009) conducted a case study to determine the efficacy of TLP in treating a 5-year-old boy diagnosed with pervasive developmental disorder–not otherwise specified (PDD-NOS), now identified as part of the autism spectrum. The child had been referred to an OT as he was aggressive towards other children, including his siblings, and showed intolerance to touch and sound. He received two months of a sensory programme created by an OT, which was described as “heavy work, deep pressure, and slow vestibular activities” (p 80). He had also received speech therapy two times per month.

After two months of OT therapy, the authors determined that the child might benefit from a listening programme. It had been noted on his OT assessments that he was sensitive to sound, and had difficult processing sound, although he had not been diagnosed with auditory processing disorder (Nwora & Gee, 2009). The child was assessed at baseline using the Listening Checklist (adapted by ABT from Madaule, 1994), which was used to gather subjective information, and the Sensory Profile (SP; Dunn, 1999). The child began the TLP protocol of 15 minute listening sessions twice per day for 20 weeks. The study authors examined overall sensory performance and receptive and expressive language, using video footage in addition to the SP and the Listening Checklist.

Video footage was provided by the child’s caregiver of three songs combining movements and props with singing, from his participation in a school music programme. The first video was taken before completing the TLP programme and the second was of another school programme following his use of the listening programme. The authors viewed the videotapes independently to identify any unusual behaviours that were not seen in the other children, and specifically any behaviours associated with ASC. Data collected were compared to establish inter-rater reliability and both reviewers were found to be in agreement on the data (Nwora & Gee, 2009). The authors noted that in the second music programme at his school, the child was no longer covering his ears and withdrawing as he had in the previous film. He was now able to tolerate sound, touch, and visual stimuli, showing eye contact with the music leader and waving to his caregivers.

The Listening Checklist (adapted by ABT from Madaule, 1994) was a Likert 4-point scale with two sections: the first related to communication, and the second related to motor skills, plus skills related to behaviour and social adjustment. It is not normed and the authors report it was used to gather information from the caregiver's perspective. The SP (Dunn, 1999) evaluates sensory processing and has 125 statements the caregiver rates on a 5-point Likert scale ranging from always to never. The investigators (Nwora & Gee, 2009) found that after completing the listening protocol, the child exhibited positive improvements in sensory processing, expressive and receptive language, motor skills, and social adjustment. In general on the Listening Checklist, improvement was noted as changing from *often* to being noted as *sometimes*. His language and comprehension had improved from reports that he had difficulty understanding, to rarely having any difficulty.

The SP summary for the child before the intervention had shown near global dysfunction. The greatest change was in his emotional reactions, which had been labelled *definite difference* at baseline but were now labelled *typical*. The authors (Nwora & Gee, 2009) point out that by using the listening programme, the child's overall skills and social adjustment improved, allowing the speech therapist and the OT to reduce their levels of intervention to consulting and monitoring.

A single case can never be generalized to a larger population, but it does provide a starting point and a case study can often provide extra details on the experiences of the therapist, caregiver, and child. The Listening Checklist is not a norm referenced assessment and was provided by ABT, the supplier of the programme, but as it uses a Likert scale, was able to show levels of change over time. The standardized SP is often used by OTs and allows a child's abilities to be rated as typical, and showing a likely, or definite difference. The caregiver completed both assessments, and the use of videos, which were reviewed by the investigators, provided a more objective review. However, it is possible that some improvements may have been age-related developments. The authors (Nwora & Gee, 2009) do not provide a timeline for the videos, only that they were taken pre and post intervention. They do not report follow-up data or observations although this may have been shown in the video, depending on the timing of the second school music programme. The authors suggest that while a case study is limited, this type of exploration is needed in treating individuals with ASC, and is a stepping stone for further research.

A single case study was undertaken by Gee, Thompson, and St. John, (2013) to determine if 10 weeks of TLP might reduce sensory over-responsivity (SOR) while also decreasing self-stimulation behaviours in a 7 year old ASC female. She was selected for the study as her SOR was interrupting her daily routines, described by her caregiver as interfering with "playing, social interaction, feeding, sleeping, self-help and self-regulation" (Gee, Thompson, & St. John, 2013, p. 14). Two measures were used, the Sensory Processing Measure (SPM: Parham et al., 2007b) and the auditory portion of the SensOR Scales (Schooen et al., 2008).

The child's behaviour labelled as self stimulation, was her abnormal visual gaze, described as moving her iris to the left without rotating her head in response to auditory stimuli. The behaviour was tracked by counting the times it occurred during the administration of the SensOR Scales, a time when various sounds are presented while the child completes various tasks, such as identifying sounds (blender, clock, barking dog, and others) and blowing a whistle. Behaviours are classified as negative or positive and all sessions were video recorded, then scored by two investigators. The duration of the self stimulation behaviour was timed using a stopwatch.

Graphs illustrated data analysis by noting changes in the level and direction of trends. Sensory processing and auditory processing scores showed improvement and the SPM (home form) showed the caregiver perceived the child's processing abilities worsened when the listening stopped. The self stimulatory behaviours had a downward trend while listening, with no behaviours noted in the observation session during the second five weeks of listening. The behaviours increased slightly after listening stopped at 10 weeks, although they were observed as less frequent and for a shorter time. (Gee et al., 2013).

Gee et al. (2013) expressed concerns that the SensOR scales may have interfered with the impact of the programme, as the child may have habituated to the sounds in the scales. The protocol for this study was 10 weeks, although recommended minimum listening time is given as 20 weeks. However, the programme did provide evidence that TLP had a positive effect on improving overall sensory and auditory processing, as well as reducing the self-stimulatory behaviour for the child. In this case the behaviour was interfering with many aspects of daily life and relief would be especially relevant for the caregiver and family.

Sensory over-responsivity (SOR) was assessed for three ASC children in a case control study by Gee et al., (2015) to determine if TLP might reduce negative sensory reactions. The participants each had demonstrated auditory SOR that was reported to be severe enough to interfere with daily routines. Criteria for inclusion in the study included the following: aged 5 to 10 years, a diagnosis of mild to moderate ASC and SOR to auditory stimuli, and an ability to tolerate wearing headphones for a minimum of 15 minutes. A caregiver questionnaire, the Sensory Processing Measure or SPM (Stewart, 2010), gave an overall score, and a subtest for auditory sensory processing was also recorded. The Sensory Over-Responsivity (SensOR) scales

(Schoen et al., 2008) were also used. Baseline scores were established over a four to five week period during 20 minute observation sessions in a university-based outpatient clinic. Ten weeks of twice daily 15 minute listening sessions were initiated at home and overseen by the caregiver. At the end of the listening phase, four weekly observation sessions were detailed and video recorded, then coded by two raters who were blinded to the session. A second 10 week protocol then began, ending with a four week observation and testing period in the clinic.

The frequency of positive behaviours was noted on a scale to show trend lines for each participant at baseline and after the listening intervention. Each participant demonstrated a different response to the programme. Gee et al. (2015) reported that Case A had the most severe auditory SOR at baseline and showed the largest improvement. Case B had the most limited SOR improvement, while Case C appeared to show improvement temporarily during the listening protocol. The improvements included a decrease in the frequency of behaviours related to sensory processing and improvement in auditory sensory processing.

The SPM asks for caregivers' perceptions of their child's progress. Case A's caregiver did not report similar improvements in behaviour as those recorded on the sensory assessment (Gee et al., 2015). Case B's scores were minimal on assessments, but the caregiver reported improvements in both auditory and overall sensory sensitivities. Case C's caregiver reported improvement in auditory processing while the assessment scores indicated improvement in overall sensory sensitivities. The caregiver reports underscore the need to find assessments that measure all the expected changes for the intervention and the importance of caregiver or individual feedback.

Gee et al. (2015) concluded there are positive trends for each case, and although results were mixed, TLP may be a valuable intervention. In this study, the most severe case at baseline showed the greatest improvement. Level of severity may be one of the factors indicating a best responder for the programme. It should be noted that the suggested protocol is 20 weeks of continuous listening, however the study divided listening sessions into two parts of 10 weeks each, with a four week break in between. Gee cautions therapists to scrutinize any programme and attempt to align the appropriate therapy with the selected programme, the family context, and their financial resources. He concludes that more rigorous research is needed to assess the impact of the listening programme.

Another case study looked at individuals with profound and multiple learning difficulties (PMLD) who are defined as having more than one disability, and have difficulty communicating, with most individuals at a pre-verbal level. Most communication is observed by regarding facial expression, movements, and eye gaze. Many will have severe sensory or physical disabilities as well. Francis (2011) states she had carried out a successful pilot study using TLP in 2007 with one child who had PMLD. TLP appeared to improve the child's ability to interact, regulate her mood, and respond to sounds.

This single case success led Francis to create a larger study with this population to determine if TLP would be able to improve attention, concentration, and social abilities as well as decrease anxiety. A secondary aim was to determine the effect of regular classical music listening versus TLP on these behaviours. The study took place at a residential school in the UK for children with PMLD who could tolerate sounds, but who had no unstable medical conditions, profound hearing loss, or uncontrolled epilepsy. Twelve single case study participants, ages 9 to 19 years were recruited. It was noted that five of the participants had Rett syndrome, two had cerebral palsy, three acquired brain injury, and two congenital abnormalities (Francis, 2011). A speech and language therapist (SLT) had assessed all students using the communication section of the Profound Education Curriculum and Assessment tool before the study began.

Few assessments for communication exist for PMLD children so a decision was made to use procedures similar to those used by SLT's at the school. The four methods of assessment were video recording, observational recording during listening by staff, the Profound Educational profile (P.E.), and a questionnaire completed by family members, therapists, and care staff at the end of the 20 week trial. The study used a cross-over design with random allocation to 4 weeks listening to classical music either pre or post intervention (Francis, 2011). The primary investigator and observers were blind to the allocation. A 15 minute listening time was set aside during the school day for each participant.

The most reliable recording method proved to be the video analysis. As a result two participants, one in each group, were excluded due to human error resulting in incomplete video data. The investigator (Francis, 2011) reported that 8/10 participants had a positive behavioural outcome, while 5/10 participants showed increased levels of engagement with classical music alone. No attempt had been made to separate children based on diagnosis, but it was noted that learners with Rett syndrome showed the most positive changes in mood and engagement. The author states this was unexpected, as change was noted in spite of health issues resulting in two of the Rett learners being hospitalized and missing two weeks of listening. Another learner with Rett syndrome had sleep cycle difficulties and had slept part way through many sessions, yet in the areas measured, still showed improvement.

At the time of the study, Rett syndrome was listed in the DSM-4 as an autism-related condition, along with Asperger syndrome and childhood disintegrative disorder. In the DSM-5, if a child with Rett syndrome also meets the criteria for ASC, the diagnosis would now be ASC Associated with Rett Syndrome (Ehret & Berking, 2013).

While questions were asked about the project as a whole, the questionnaires received from parents, school and care staff (N = 17) supported video observations in 7/8 cases. The yearly P.E. profile, recorded after the intervention, was compared to two previous years, to see if any learners showed greater improvement than expected, to determine if change should be attributed to normal maturation. All five Rett syndrome leaners had a noticeably higher percentage rate of increase than previous years (Francis, 2011) as well as one child with acquired brain injury.

Mood did improve some with students listening to classical music only, but changes in social engagement occurred only after TLP had begun. The author reported her listening observations, that four listeners could not tolerate headphones and/or music, and the greatest sensitivity was with TLP music. It should be noted that the Spectrum edition of TLP, used in the present study, was not available at this time. The Spectrum edition was said to be created for sensitive listeners and is now recommended for ASC and brain injury. Although classical music listening was an unfamiliar experience for some listeners, nearly all enjoyed or showed tolerance by the end of the study with the exception of one learner who displayed an extreme negative reaction to the Mozart recording. Francis (2011) noted that the Observation Recording assessment was not sensitive enough in recording changes in mood and engagement during listening to be useful, and in future studies, additional rating options should be added.

Although the results are mostly observational, PMLD is an especially challenging group to assess and treat and the author showed care and resourcefulness in designing a workable study. The use of several assessments showed consistent agreement between observation methods and observers. Due to the length of the listening protocol, health issues and changes in medications occurred in all learners over the course of the study. In spite of its small size and considerable challenges, positive results for the Rett group provide support for further trials using TLP with ASC children. In general those with PMLD also showed trends indicating the programme was useful, with indications those who benefited most had sensory processing difficulties.

A pilot study using TLP was undertaken at a paediatric clinic by Esteves et al. (2009) for six children, ages 3 years, 11 months to 8 years, 7 months, all with sensory processing disorder (SPD) and also with concerns of auditory processing disorder. Four of the children were receiving physical therapy (PT), occupational therapy (OT), and speech/language therapy (SLP). Of the remaining two children, one had received OT and SLP in the past, and the other had never received therapy. An OT from the clinic monitored all the children, while the individual parent implemented the listening protocol of two 15 minute sessions five days per week for 20 weeks in the home. Parents were given logs to keep track of progress and a listening checklist and observation checklist provided by ABT. Diagnoses of the children included Attention Deficit Disorder (ADD), autism, central processing dysfunction, developmental delay, and brain injury. Assessments used in the study included the Short Sensory Profile, (SSP; Dunn, 1999) several tests for motor skills, and several tests for speech and language, which were selected depending on the age and functional level of the individual child.

Results were presented for each child ending with a summary of results for all children. The child called PB in the study had the diagnosis of ASC (personal communication with lead author Esteves, 2010) and had been seen at the clinic for therapy services. Scores were compared on a listening screening tool from his last services at the clinic, to scores gathered before the listening study began, and limited change was noted. One exception was seen in upper limb coordination, which showed a change in age equivalence of 6 months. No other changes were noted before listening began.

Following the completion of the 20 week listening protocol, PB demonstrated improvement on the Beery Development Test of Visual-Motor Integration (VMI) in two subcategories. Change is measured by increases in age equivalent scores. The most significant changes were improvements in motor coordination (3 years) and visual perception (6 months). PB improved the most in bilateral coordination, visual-motor control, and response speed in motor skills, as measured by the Bruininks-Osteretsky Test of Motor Proficiency (BOT). The authors (Esteves et al., 2009) noted that PB was more able to follow directions, paid better attention, and had improved balance. He also demonstrated increased difficulty in controlling his emotions, with outbursts changing from crying to laughing.

The Sensory Profile Short Form showed improved scores in all the subcategory areas of touch, taste, smell, movement, under responsivity, and low energy. PB showed significant improvements in auditory filtering and visual/auditory sensitivity, where he moved from the category *definite difference* to *typical* (Esteves et al., 2009). Results showing gains in speech and language skills were noted in subcategories of several tests: the Receptive One Word Picture Vocabulary (3 months), the Expressive One Word Picture Vocabulary (6 months), and on the Kaufman Speech Praxis Test scores showed gains of 8 months in oral movements, 11 months gain in the category called "simple" and in the category of “complex”, PB was now able to complete the test while before listening, he had been unable to do so.

After completing the 20 week listening protocol, PB’s parents reported he had increased eye contact, better relationships with other children and adults, was more independent, showed more affection and had both increased voice quality and speaking quality. He also had improved sleep patterns, improved attention, and was less sensitive to sound (Esteves, et al., 2009).

The authors reported that, based on scores recorded from pre and post testing, all children in the study demonstrated significant improvements after completing TLP as compared to just OT therapy services alone. As the present study focuses on children diagnosed with ASC, only the ASC child’s results are given in detail here. Esteves et al. (2009) concluded that TLP, along with skilled therapies, appeared to help the children in the study to achieve his or her potential and achieve greater independence in daily life tasks and skills.

This was a small multiple case study with a variety of diagnoses. The commonality was that all cases were known to the OT clinic and five of the six children had received therapy services there. Selection was based on the therapist noting the child had auditory processing concerns and therefore might benefit from an auditory programme. The authors stated a listening screening tool provided by ABT was used, not for qualification as it is not standardized, but as a baseline measure. A number of assessments commonly used by OTs measured a broad array of sensory changes and communication skills. As the children had different diagnoses, and different assessments were used to measure change, data from all cases could not be analysed in combination. The authors did not state if the child was receiving any therapies or services in addition to OT or TLP during the 20 week protocol.

The study was a good first step to determine efficacy of TLP usage by the clinic for a variety of clients. Results do show evidence of efficacy for all participants. While the children were assessed as not making progress with OT alone, most listening protocols were followed in conjunction with some OT therapy. The results are presented as evidence that the two therapies should be used together when the need is indicated. In reviewing the case for the ASC child, the results were significantly better in a number of areas, and did not occur solely with OT therapy, providing support for the need for a larger trial to determine if TLP might be effective with ASC children.

A Quantitative Summary of TLP Efficacy Studies was undertaken by Vargas and Lucker (2016). While few studies have been subjected to peer review or undertaken only with ASC children, 15 studies had been completed with TLP. and were published on the ABT website under research (ABT, TLP Research, 2017). Ages ranged from toddlers to older adults and studies were exploratory, measuring outcomes ranging from toileting to motor coordination, auditory processing, and other features. All were undertaken with single groups which used pre and post test scores and investigated mostly by educators, speech language therapists, and occupational therapists in the US, UK, and Australia. With so many different variables, effect size was eventually determined to be a common measure that could be evaluated quantitatively, using Hedge's g formula. Studies were included that used a group of participants rather than a single case study, had formal pre- and post-testing, and had sufficient data to calculate effect size for various measures. Nine of the studies met inclusion criteria and were included in a summary.

Mean effect sizes were derived in several categories. The mean effect size for all nine studies as a whole was 0.41, which is considered a clinically significant improvement (Vargas & Lucker, 2016). Individual effect sizes ranged from small (0.23) to large (1.23). The two largest effect sizes were studies by Jeyes (2004, 2013). Jeyes' 2013 pilot study assessed only ASC children (N=12) ages 5 years 8 months to 12 years 4 months, with 11 showing improvement on auditory figure ground, and 10 showed improvement on words and sentences heard in competing noise, as measured by the Scan-C (Keith, 2000), a test for auditory processing disorders. In a questionnaire designed by Jeyes, parents reported improvements in their ASC child in varying aspects of communication, behaviour, and physical factors such as motor coordination, sleep, and improved food tolerances. Positive results were noted although participants only listened for 10 weeks, rather than the full 20 week protocol. Overall effect size for the study was 1.19, considered a large effect size based on four measures. The study was presented at Children's Complementary Therapy Network Conference, Birmingham Children's Hospital (2013), and published online at ABT's website ("Research", 2016). Data were analysed for the Vargas and Lucker summary, but the study was not published in a peer-reviewed journal.

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The largest effect sizes for outcome measures for all nine studies were for auditory factors and the smaller effects measured non-auditory outcomes such as sensory, motor, and neurological function. One other finding emerged based on the Sensory Profile (SP; Dunn, 1999), providing a mean effect size of .32 for the category sensory processing. The result followed the trend of showing that auditory factors demonstrated the largest effect sizes. The trends noted in the summary were consistent with the previous studies reviewed earlier. The authors (Vargas & Lucker, 2016) were clear in pointing out the many limitations of the studies examined. The number was small, they were exploratory pilot studies, and most were not peer reviewed. However, the summary was seen as an initial step to determine if the existing study outcomes would point the way to future research.

2.61 Summary of TLP Studies

The 11 ASC children treated as case studies above (Nwora & Gee, 2009; Gee, Thompson, & St John, 2013; Gee et al., (2015), Frances, 2011; and Esteves et al., 2009) all were reported as demonstrating trends for positive change. All were exploratory with convenience samples, most were directly related to auditory skills, social reactions, mood and emotional reactions, and all showed positive change in a number of areas. The summary of nine small TLP studies (Vargas & Lucker, 2016) was evaluated by determining effect size for each study. Of the nine studies, one assessed the effect of TLP on 12 ASC children by measuring auditory filtering, and this ASC trial showed the second largest effect size of the nine studies.

Data from the published studies noted above are limited but consistently show greatest improvement in auditory related areas, and are consistent in showing a positive trend for improvement. Given the widespread continued usage of the programme, and the lack of other proven interventions, the next step should be a randomized controlled trial. An RCT would investigate efficacy and effectiveness for ASC children beyond a convenience sample with a single person or group, and provide an examination of any group differences in outcomes for communication, social abilities and behaviours using a random sample.

3.0 Methodology for an RCT

This first RCT will assess several aspects of the experimental programme, to determine if data support the preliminary trends and anecdotal evidence reported in individual studies and in a quantitative summary by Vargas and Lucker (2016). It will provide insights into the sensory theory of autism described earlier, that sensory overload interferes with abilities and behaviours associated with the auditory sensitivities often experienced in children with autism, and if these sensitivities could be reduced, more normal learning and behaviours would occur. The experimental programme is theorized to reduce and/or normalize auditory sensitivities and associated behaviours because of the filtering and modifications in the music, and this will be tested with the partial double blind trial design using similar commercially recorded unfiltered music in an identical protocol.

It was hypothesized that improvements would be greatest in the experimental listening group as compared to the passive control group with no listening. Improvements in the three domains of Communication, Social Abilities, and Behaviours are expected to occur within 20 weeks and were measured before and at the end of the protocol. The three domains contain items that have been associated with auditory sensitivities, as outlined in the literature review. If the programme is able to help reduce the threshold of a child's sensitivities to sound, the associated abilities and behaviours that are believed to be affected by the sensitivities, should show improvement as well.

Secondly, the active control group was expected to experience greater change than the passive control group, but less change than the experimental group. This element was included to determine if filtering and modifications to the music might be associated with change rather than listening only to unfiltered music using the same protocol. Music is commonly used for distraction and relaxation and comparing the two listening groups to the control group should indicate if similar commercially recorded music might also be associated with the expected improvements.

Third, the experimental programme was tested at 40 weeks to determine if any reported changes had been maintained in the listening groups. The cut-off of 20 weeks is recommended as a minimum listening time but in a real- life setting, the therapist or educator will generally incorporate the programme as part of their overall treatment plan. Based on the child's response and the severity of their sensitivities, the listening time may be adjusted and the therapist may recommend that either all or sections of the programme be repeated. For this initial RCT, assessing level of change at 40 weeks will show if any improvements are maintained without the use of the programme. This will answer the research question, do changes occur only while listening, or will changes maintain after daily listening has ended.

The ability to listen and accurately process sound is considered a primary pathway for language and learning. Any difficulties with processing sound will result in communication challenges for a child in the home, at school, and in other social settings. Filtered music listening training is based on the idea that focused listening through headphones to a structured programme of recorded music that has been filtered and modified to emphasize and isolate certain features, will re-educate the auditory pathway and create measurable change for the listener.

Bogdashina (2013) pointed out that sensory dysfunction has been described as nearly universal in ASC, and is seen early in a young child's development. It often serves as a flag to parents that their child should be screened for ASC (Wiggins et al., 2009). Bogdashina referred to this evidence as a sensory theory of autism. This sensory dysfunction is especially true of auditory sensitivities. Abnormal reactions to sound may be observed in young children as a lack of any response to sound, or a child may be very disturbed by the sound and react by putting his hands over his ears. A child may also react by seeking sound stimulation or have difficulty focusing on one sound in background noise.

More than one of these responses may be seen in the same child in different circumstances. This constant distraction from both environmental and speech sounds may reduce the ability of a child to focus and to develop communication skills, to interact socially with family and friends, and to learn adaptive behaviours that would be age-appropriate for a typically developing child. The sensory theory suggests that if sensory sensitivities could be reduced, the severity of symptoms related to auditory input should decrease, distractions would be reduced, and more normal development and learning would occur. Children develop coping strategies to protect themselves from overwhelming sensory distraction, such as avoiding noisy environments, and this is often seen as anti-social activity. Recently the field of occupational therapy has focused on studying the complex reactions to sensory sensitivities in ASC children, including auditory sensitivities and the associated behaviours in order to have a better understanding of how to treat these symptoms (Tomchek & Dunn, 2007).

Few academic studies with rigorous tests for efficacy exist for filtered music listening programmes used for ASC children. The 2011 Cochrane review of auditory integration training and its efficacy for ASC (Sinha et al.), described in detail in section 1.5, reviewed just 7 studies of 19 assessed for eligibility, as only randomized controlled trials with all participants diagnosed with autism were eligible. Other challenges observed in the search were that too many different assessments were used, different outcomes were measured, and data presented were sometimes unusable. The filtered listening programme used for the present study, TLP by Advanced Brain Technologies, was not mentioned in the Cochrane review. While published evidence in academic journals for using TLP is not strong, preliminary evidence (Nwora & Gee, 2009; Gee, Thompson, & St John, 2013; Gee et al., 2015, Frances, 2011; Esteves et al., 2009; and Vargas & Lucker, 2016) does show consistent positive trends. An RCT would help to determine if TLP Spectrum, an edition developed specifically for ASC and other sensitive listeners, might provide some relief from sensory symptoms for children and their families.

3.1 Theoretical Basis and Hypothesis

The focus of this study will be to measure communication, social abilities and behaviours that have been reported in previous studies as showing trends for improvement and/or have been reported to improve anecdotally by parents. The study was designed to determine if daily use of the experimental programme over a 20 week period would produce significant change as compared to a passive control group who had no intervention. The study design controlled for both the effectiveness of the intervention and the music. To confirm if any reported changes might be attributed to the filtered music programme, or would also occur with listening to unfiltered music, a partial double blind condition was created between the two listening groups, an experimental and an active control. Music is commonly used for distraction and relaxation, and comparing the two listening groups should determine if filtering and other modifications of the programme can be associated with change in the areas assessed.

It was hypothesized that improvements would occur in communication skills including speech and language, social abilities including interaction in the family and community, and adaptive behaviours including health issues associated with sensory sensitivities, and that changes would be greater in the experimental listening group as compared to the passive control with no intervention. Changes were expected to occur within the 20 week protocol and were measured before and at the end of the protocol. The active control group was expected to experience greater change than the passive control group, but less change than the experimental group.

The study was also designed to measure change at a 40 week follow up, to determine if any reported changes would persist over time. Several other factors were also measured. Severity of symptoms was measured at baseline to ensure that participants in each group were comparable. Symptoms were measured again at 20 weeks to determine if there might have been a decline in severity, as severity of symptoms related to auditory input are theorised to decrease over time with regular exposure to the auditory stimulation in the experimental programme. Parental stress levels were assessed at baseline and at 20 weeks, to determine if stress levels in areas most important to the parent of an ASC child had decreased. This was especially important as the parent was overseeing the 20 week programme in their homes. Levels were compared between the groups to determine if any reported changes might be associated with the experimental programme.

3.2 Selected Measures

Interventions created for use with ASC children are generally designed to reduce the degree of impairment in specified areas and the Likert scale format of all the chosen measures for the current study allowed this sensitivity to change to be quantified. Four measures were selected that could be easily completed by a supervising parent as the study was parent-directed, with all listening done in the homes of families around the UK. Three of the measures were created specifically for children with ASC, and a fourth, the Vineland Adaptive Behaviour Scales-II (Sparrow et al., 2005), is a measure often used in schools for any child who might be developmentally delayed. The first three measures were recreated online using the Bristol Online Survey Tool, and parents were sent the link in a weekly email, with links for each measure also given in the guidebook for the study (Appendix H).

3.21 Vineland Adaptive Behaviour Scales – II

The Vineland Adaptive Behaviour Scales, Second Edition is a paper booklet and the version to be completed by parents and caregivers was selected as appropriate for the study. While not specifically designed for autism, the Vineland is recommended by Cunningham (2011) for use with ASC children. It was selected as the primary assessment, to the used at baseline and after completing the 20 week protocol. The Vineland has questions that are developmentally and age appropriate, assessing every day functioning in the areas of communication, social abilities, and behaviours that are hypothesized to change from using the experimental programme. Specifically communication is described as receptive, expressive, and written, and social skills are described as interpersonal relationships in the home and community. Adaptive behaviours, which are also under the category of social skills, include the ability of a child to change activities easily, and express socially appropriate behaviours in a variety of situations. Assessing change in each of the three categories will answer the question, does the experimental programme bring about improvement as measured in the categories of communication, social abilities, and adaptive behaviours greater than no intervention? Assessing the categories separately will allow the investigator to understand where change has occurred and to what degree. Each item is rated on a 3 point scale as *never*, *sometimes* or *partially*, and *usually*. The Vineland-II took the most time to complete, about 60 to 90 minutes, and was posted to the parent with a return, pre-paid addressed envelope.

3.22 Autism Treatment Evaluation Checklist, ATEC

The Autism Treatment Evaluation Checklist (ATEC) was developed by Rimland and Edelson (1999) at the US Autism Research Institute, to assess ASC treatments considered complementary and/or alternative. The ATEC was created for individuals beginning at two years of age and above, and requires no special training to administer or complete. The assessment has four categories labelled Communication, Sociability, Sensory and Cognitive Awareness, and Health and Physical Behaviour. The ATEC was selected for use in the present study as it was created specifically for use in assessing interventions for autism, is easily completed by a parent, and three of the subscales specifically cover the factors being measured. As it takes only 10-15 minutes to complete, it was also used weekly as a way to maintain contact with parents throughout the 20-week protocol to encourage compliance and as the follow up assessment at 40 weeks.

The ATEC was compared with the Childhood Autism Rating Scale (CARS), an established measure with high validity and reliability used by professionals to measure autism severity. Parental ratings of the ATEC showed a significant correlation with professionally rated CARS scores. A significant correlation was found between total scores, as well as between the four ATEC domains and CARS scores. The authors (Geier, Kern & Geier, 2013) pointed out that the fourth category of the ATEC, which focuses on behaviours, also includes health and physical issues associated with ASC children, and these are not often addressed in other autism assessments. A number of these behaviour and health issues have been associated with abnormal auditory sensitivities, such as toilet training (Yip, Powers & You, 2013), and anxiety and repetitive motor behaviours (Mazurek et al., 2013), as were discussed in the literature review and may also improve. The measure is a useful choice for determining if the experimental programme will have an expected effect, as reported anecdotally, on all items in the Behaviour subscale.

A limitation of the ATEC was revealed in a study by Magiati et al. (2011). The authors show that the Communication subscale is somewhat limited, that the ATEC is likely to be most beneficial in measuring change in children with less developed communication skills. As the Vineland was considered the primary measure and has extensive questions for this factor, this weakness was not considered a major drawback in also using the ATEC. A

3-point Likert scale provided measurement for the first three categories from *not true or not descriptive* to v*ery true or very descriptive* and a 4-point Likert scale was employed in the fourth category from *not a problem* to *serious problem* (Appendix J). The checklist is simple and short enough to complete in about 10 to 15 minutes by a parent. It was recreated online and parents were asked to complete it weekly to encourage compliance with regular listening, to the end of the 20 week protocol, and then at 40 weeks, to determine if any reported gains continued, were maintained, or diminished when the programme protocol was completed.

3.23 Cambridge Autism Quotient, AQ-Child

The Cambridge University Behaviour and Personality Questionnaire for Children, known as the Autism Quotient or AQ-Child, (Auyeung et al., 2008) was selected to measure the severity of autistic traits, first to assess if children in the three groups were comparable before starting the study. The authors recommended that the assessment also be used as a measure of change over a longer time period, to understand how stable autistic traits might be as a child grows. The stated goal for the experimental programme is to reduce the severity of auditory sensitivities, and these are associated with a number of the autistic traits and behaviours measured in the AQ Child. The sensory theory of autism predicts that with a reduction in sensory sensitivities, severity of symptoms seen as autistic traits should decrease. A pre and post analysis of results may provide additional support for the concept of a sensory theory as well as for the intervention, if a reduction in the severity of traits is seen, as compared to no intervention or from unfiltered music listening.

The AQ Child version has 50 items (Appendix I) and was adapted for children ages 4 to 11 years from the adult and adolescent version by Auyeung et al. (2008). The items fit into five categories of 10 items each: social skills, attention switching, attention to detail, communication, and imagination. Ratings for each item range from *definitely agree* to *definitely disagree* on a 4-point Likert scale with higher scores indicating severity. Scores range from 0, no autistic traits, to 150, severe autistic traits, with a cut-off score for autism of 76. The assessment takes about 25 minutes to complete. It was recreated online and parents were requested to complete it at baseline and after 20 weeks.

3.24 Autism Parenting Stress Index, APSI

Parents of children with autism report four times the mean level of stress than a parent of a neurotypical child, and double the stress reported by a parent of a child with a developmental delay (Silva & Sshalock, 2012). This makes measuring parental stress an additional valuable indicator for success of any ASC intervention. The Autism Parenting Stress Index–Short Form (APSI) was designed by the Qigong Sensory Training Institute to address parental satisfaction, to determine family stress levels before and after an intervention, and was provided by the institute upon request to the investigator. For the present study, parents are overseeing daily listening and completing assessments, and for the programme to be truly effective, their role should not create greater stress. The treatment must fit into the family routines, be reasonable to implement, and if changes are seen, may diminish levels of stress for the family greater than the active control or no intervention.

The institute combined three scales, Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child, to yield a total stress score. The parent was asked to rate the amount of stress a topic causes to them and/or their family, such as *your child's social development, aggressive behaviour (siblings, peers), potty training*, *concern for the future of your child being accepted by others*, and so forth. Stress ratings range from *not stressful* to *so stressful sometimes we feel we can't cope* on a 5-point Likert scale (Appendix K). The APSI (Silva & Sshalock, 2012) was designed for parents of children

12 years and younger. With just 13 questions, it takes about 5 minutes to complete. The APSI scores will answer the question: Will the use of the experimental programme for the required protocol reduce stress in areas known to cause concern to an ASC family greater than the active control or no intervention?

3.3 Experimental Design

The full study was a randomized, controlled, partial double blind design. Groups were identified only as A (experimental programme), B (active control programme), or C (passive control, no listening). The two listening groups used identical equipment, bone conduction headphones and iPods with the same format for the daily music listening modules. Participating families were assigned an identification number in the order that the signed participant agreement forms were received and this ID number was used along with the family surname in correspondence. Families were told they would be able to experience the experimental programme after the study ended if their child did not receive it during the study.

A feasibility study was first undertaken to test the many details of the study design, and the materials needed to implement it. Participants' feedback would allow a review of aspects of the design, to determine if changes would need to be made for the full study. The feasibility study is described in detail in section 3.6.

3.31 Inclusion and exclusion criteria

Criteria for inclusion in the study included an official diagnosis of ASC from a qualified professional. As some children may have been diagnosed before the new Diagnostic and Statistical Manual, DSM-5, was released with its new description of ASC, eligibility included a diagnosis of Asperger's and pervasive-developmental disorder-not otherwise specified (PDD-NOS). Children must have been between the ages of 4 and 8 years of age when the study began.

Exclusion criteria included a child having another major genetic or medical diagnosis such as Down syndrome, Fragile X, or Tuberous Sclerosis. The participating parent had to have adequate facility in English in order to complete the assessments. The study was not open to families outside the UK. As to other confounding variables, parents were asked to not be involved in any other intervention for their child during the time of the study, apart from what took place in normal school sessions throughout the year.

3.32 Ethics approval

The study was submitted for review to the Clinical Psychology Ethics Research Panel at the University of Edinburgh. Participants in the study were children aged 4 to 8 years. However, all contact with the family was solely with the supervising parent; the investigator was not in contact with any of the children in the study. The supervising parent was required to submit a signed form (Appendix C) giving consent for their child to participate. It should be noted that children at this age with ASC may be unable to speak, read, or understand. The parent was asked to confirm their child had received a diagnosis of ASC by a qualified health professional and that the child was not involved in another intervention at the time of the study.

The intervention features music by well known classical composers, primarily Mozart and Haydn, that has been filtered and modified in various ways the creators of the programme believed would improve the listener's ability to focus, listen, and process sound more accurately. The control programme consisted of commercial recordings of Mozart in the same format with no filtering or other modifications. Parents were advised only that the study was comparing two music listening programmes. No adverse effects were expected as classical music listening is generally considered a safe and pleasurable experience, and earlier editions of the experimental programme have been used by trained therapists for approximately 18 years.

Guidelines were given to each parent helping them to begin the daily listening protocol of two 15 minute listening sessions, 5 days per week, for 20 weeks. This included headphone usage, suggested activities, advice on safe volume levels, and monitoring their child closely as they began the programme to ensure comfort and compliance. Parents were cautioned to temporarily discontinue their child's listening in case of ear infections or illness and to continue listening when the child was well. They were given the investigator's email and encouraged to contact her if they had any questions or concerns.

No direct financial compensation was offered for participation. However the intervention is available commercially and including a therapist's supervision plus listening equipment (iPod, digital amplifier, and bone conduction headphones), has an approximate value of £1500. Listening equipment was collected at the end of the study. All families who did not receive the intervention during the study were offered the opportunity to receive it after the study had concluded.

The submission was independently reviewed and approved on 20 December 2012 (Appendix D).

3.33 Recruitment

A website was created at www.autismlisteningstudy.com (Appendix E), plus a brochure (Appendix F), and poster (Appendix G) were created to provide information including eligibility and how to enrol. Participants were first recruited for the feasibility study, described in detail later. When recruiting for the feasibility study, it was discovered that numerous online local support groups for parents of children with ASC exist in the UK. Contacting parents directly through these groups, and directing them to the study website was determined the most efficient and timely way to recruit participants whenever possible.

It was determined that 60 participants total would provide 20 in each of the three group and this would be adequate for the study. For a parallel design showing an experimental therapy is greater than a control group, Chan (2003) shows a required sample size of 20 participants for a confidence interval of 95% and 80% power.

When recruitment was begun for the full study, a number of attempts were made to recruit participants in Edinburgh and surrounding areas. An autism treatment charity in Edinburgh, called Autism Treatment Plus, posted information in their blog and newsletter, with a link to the study website for more information. A large response produced the first 12 eligible participants, but all were located outside of Edinburgh. The pattern of participants being outside of Edinburgh continued throughout the long recruitment period of approximately 10 months for the full study.

A request to the National Autistic Society (NAS) to be included on their research website with notification in their newsletter was approved. No inquiries resulted after posting, so over 150 NAS parent support groups throughout the UK were then contacted individually, asking the area parental contact to pass along information and a link for the study website to their members. Later, health care professionals who worked with autistic children were contacted via email, autism parent groups on Facebook, and local autism websites were all asked to post notices referring interested parents to the autism listening study website (www.autismlisteningstudy.com).

A second attempt to recruit in Edinburgh was made with printed brochures placed in soft play areas that sponsored autism-only play times. Permission was granted from the Service Manager, Professional Services for the Scottish government, to provide information to special needs contacts in schools in Edinburgh, to pass along to parents. However the schools that were contacted requested more forms be completed with additional details about the study, and the extra efforts were deemed too time consuming by the investigator.

After 48 families had eventually been enrolled, recruitment seemed to stop in spite of continued efforts. In order to reach the goal of 60 children, several families who had inquired, but whose children were not yet age 4 or whose child was age 9 and therefore ineligible at the time of inquiry, were contacted and offered a place resulting in two participants over the initial age range, one age 9 and one who had just reached age 10. A colleague presented information in her autism workshop in Glasgow about the study, and 6 more parents were enrolled bringing the total to 63, with 21 children in each group. The recruitment effort was intensive, and the final participants enrolled about the time the first participants were finishing their 20 week listening protocol.

A parent was required to sign a form in two parts to enrol (Appendix C). The first part was a Parental Permission form asking for personal and qualifying information and the second part was a Loan of Equipment section stating agreement that the listening equipment was on loan, would be maintained in good condition, and returned to the investigator at the end of the study.

Over a 10 month period, 152 families, (8 with twins or siblings with ASC for a total of 160 children) asked to take part. Sixty-one families signed Permission to Participate and Loan of Equipment forms including two who signed forms for each twin, making a total of 63 children in the full study.

3.34 Randomization of participants

When signed forms were returned, parents were notified that they had been accepted. Families were assigned a number in the order accepted, from 1 to 63, and the family surnames and numbers were given to a colleague. The numbers were randomized using the "Research Randomizer," part of the Social Psychology Network. A number generator produced lists, randomly assigning each number to one of three groups: listening group A, listening group B, or control group C (*n* = 21 for each group).

3.4 Study Materials

Parents were provided with an Information and Guidelines booklet (Appendix H). All groups were given instructions about completing the assessments. Three of the assessments had been recreated online to make it easier for the parent to comply. The two listening groups' instructions included information about helping their child begin listening and adjusting to headphones, suggested activities while listening, a listening diary, an iPod marked only A or B, bone conduction headphones with amplifier, 40 AA batteries, and if needed, a wall plug to recharge the iPod. The batteries were determined important to ensure that the parent would be able to more easily complete the 20 week protocol without interruption.

If a child had abnormal sensitivity to touch, wearing headphones for the first time might be a difficult adjustment. The guidelines gave a number of suggestions for getting started for a child with tender ears, such as a parent wearing headphones to model the experience, trying for only a few minutes the first time, distracting the child with toys, offering an incentive at the end of a specific time, and so forth. Websites with suggestions for children who have difficulties with touch were provided in the Guidelines booklet: www.sensory-processing-disorder.com and http://www.childrensdisabilities.info/sensory_integration/activities-tactile.html.

Under normal circumstances, a trained therapist will generally help the parent and child to get started with the music listening programme. The child is generally already known to the therapist, often an Occupational Therapist, and they will spend additional time with the parent and child to answer questions and assist the child to start listening. In this instance, all information and guidelines were given to the parents in a Guidelines and Instructions booklet in order to fill this gap. If the parent had any additional questions, they were directed to contact the researcher at her university webmail address, given in an email and also in the Guidelines booklet.

3.41 Experimental listening programme.

The TLP Spectrum Provider Reference Document (ABT, 2012, presented in Appendix B) describes the music, design and modifications for the Spectrum edition and is not available to the general public. The reference document was created by ABT for use in their provider training courses (open to professionals for a fee) and was made available to the investigator. The reference document describes the Spectrum edition as specialized for sensitive individuals based on the company's feedback and experience with the previous edition, and is recommended for those diagnosed with ASC. The stated goal for the Spectrum edition is to desensitise and reprogram the listener's emotional memory and anticipation, so sound can become associated with calm and comfort by using filtering, specific modifications, a graduated listening sequence, and greater use of low frequency sounds described as calming.

The recorded music in TLP Spectrum, the experimental programme, was selected from the works of the following composers: Mozart, Haydn, Danzi and Vivaldi. The music was then arranged and performed in a recording studio by the Arcangelos Chamber Ensemble specifically for the company's listening programmes (ABT, TLP Spectrum, 2016). The music was recorded at 24-bit 192 kHz high definition. The music was then extensively arranged and edited in post production, according to the creator's (Alex Doman, CEO of ABT) ideas for improving listening training and to fit the timing for each 15 minute segment.

The Listening Programme design consists of 200 15 minute modules (50 hours of listening), suggested to be the minimum recommended protocol, which was used in the present study. The programme can be repeated (100 hours of listening), and then used as needed. The three part modular design, called the A/B/C design, allows for gradual change, with each module having different levels of filtering and modification. The first 5 minutes (A section) of each 15 minute module begins with unfiltered and unmodified music, the next

5 minutes (B section) progresses to various levels of filtering and modification throughout modules 1 to 200, and the final 5 minutes of each module (C section) returns to unfiltered and unmodified music as each 15 minute segment ends (Reference Document, Appendix B). Each 15 minute module may have one or several different compositions, blended together to fit the 5 minute A/B/C modular design.

Attention and listening training is provided from the first modules of the Spectrum edition, by creating arrangements of the music designed to bring one instrument to the attention of the listener for a short time, then highlighting other instruments through changes in volume and timing throughout the module (Reference Document, Appendix B). The programme was developed to provide novelty to keep a young listener's attention and to encourage active listening training challenges. The challenges might include timing entrainment, focus on different filtered frequency zones, sound location training, and volume changes. The listening modules are structured so that changes are introduced in a gradual sequence occurring throughout the 20-week listening experience.

In the recording industry, audio engineers regularly use various audio filters to remove unwanted noise that may interfere with speech perception or may have occurred during recording of live music. TLP follows the ideas of Tomatis cited in detail earlier, that focused listening to a specific frequency range is believed to re-educate the ear and brain, so that each zone or frequency range would be more clearly heard and understood. The reference document (Appendix B) states that several types of filters were used on the recorded music in the post-production process to create TLP Spectrum. The first modules, 001-020, are unfiltered using full frequency sound within the normal hearing range of 20 Hz to 20,000 Hz. This is considered an introduction to the structured music listening experience and to listening through headphones.

Filtering progression begins with low pass filters, used to create Modules 021 to 060. A low pass filter allows low frequencies in the music to pass through and be heard, but cuts off sound in the upper frequencies to focus listening on the range of 20 Hz to 1,500 Hz.

Both low pass and band pass filters were used in creating modules 061 to 150. A band-pass filter focuses hearing on mid range frequencies of 500 Hz to 5,000 Hz, cutting out bass and treble frequencies. From observing his patients, Tomatis believed a band of frequencies in this range were used for communication, including speech and language (Sollier, 2005, p. 197).

High pass filters were used for modules 151 through 200. A high-pass filter does the opposite of a low pass filter, stopping low frequencies in the music from passing through and being heard, while allowing the mid to high range of 750 Hz to 20,000 Hz. Intensity gradually increases through each of the ranges (Reference Document, Appendix B).

The second 15 minute module (module numbers 2,4, 6, and so on up to 200) of the daily 30 minute listening protocol, was created with low-pass filters, as low frequencies have been described as having a calming effect (Liu et al., 2003). The reference document (Appendix B) also describes how a sweep audio filter was used throughout a 15 minute module, to introduce each point in the programme that a new level of filtered music was introduced. Rather than removing a specific band of frequencies, a “filter sweep” moves through the music and cuts the frequencies from top to bottom and back to top, sweeping throughout the frequency range. This was described as providing a gradual introduction to hearing filtered music.

Surround sound and movement *was created using* a technology called Dolby Headphone ® © and is explained as bringing realistic surround sound to listeners using any type of headphones, by an encoding process in the music. The listening experience can be described as though the sound is coming from the space around the head and beyond the headphones.

Dolby Headphone technology was used to create an unusual aspect of the experimental programme (Reference Document, Appendix B). For ABT's programmes, individual instruments were recorded separately in soundproof rooms in the studio. During post production, the music could then be placed in individual virtual locations within a 360 degree space, using the Dolby Headphone encoding process. Later modules in the programme used the technology for surround sound, but with individual sounds of instruments highlighted, rather than blended sound, as normally occurs using stereo headphones. A process was also developed by the company to allow individual sounds to move, as occurs in a natural environment, such as the sound of a moving car or barking dog, and was named Spatial Surround Dynamic. The movement of sounds was sometimes added in modules found later in the programme and is always maintained at a slow pace so as not to startle sensitive listeners, but to allow them to comfortably listen to the change and follow the sound movement.

3.42 Active control listening programme

Most of the other commercial filtered music programmes follow the work of Tomatis (listed in Appendix A) and use commercial recordings of Mozart that are filtered according to the ideas of the creators. ABT's programme uses compositions by Mozart, Haydn, Danzi, and Vivaldi and all are extensively arranged and recorded specifically for the programme. In addition, the compositions are cut to fit the A/B/C design and 15 minute segments, which may contain small sections of several different compositions blended together within each 15 minute listening segment of the programme. These are considered modifications to the programme that may enhance its effectiveness and the music is not available as a commercial recording. Compositions by Mozart with no filtering or modifications were selected as a viable alternative to use as the active control or second listening programme for the study, to determine if the same structured listening protocols with similar unfiltered music would affect change.

The active control listening programme was created by ABT's audio engineer several years earlier when requested for a proposed study at the University of Sheffield. Recordings of Mozart by The English Concert, conducted by Trevor Pinnock, were purchased. No attempt was made to find specific pieces or arrange them in any specific order. As the music was to be divided into 15 minute listening modules, selection was generally based on finding pieces or sections of pieces that would fit this time length. These modules were numbered for the present study from 1 to 200 so the active control listening programme would be identical in presentation to the experimental listening programme.

3.43 Creating a partial double blind condition

The experimental and active control listening programmes were loaded onto Apple iPod Nanos by the company at their US office and labelled only A or B with a sticker affixed to the back, to create a double-blind condition for the study. This was a partial double blind condition, as the passive control group did not have headphones or a listening programme. The iPod screens for both programmes gave identical information and numbering of the modules. The identity of the programmes was revealed to the investigator at the end of the recruitment period in October 2014 after 63 participants had been recruited and all randomly assigned to a group.

Un-blinding the investigator at that time became necessary because of the complexities of providing and mailing equipment for the families over the long study timeline. Some families were completing the listening portion of the timeline as the last recruited participants were beginning. Those who had been allocated the control programme would need to return the iPods so they could be reloaded with the experimental programme. This could only be accomplished by returning the iPods to the US supplier for reloading. The identity of the programmes was only provided to the participants at the end of the 40 week period, when all requirements of the study had been fulfilled.

3.44 Listening equipment

All past TLP editions were created using portable listening equipment, first recorded onto CD's so that they could be used in the home. Newer editions incorporated more current technology in their creation and in their use, moving from CDs, to iPods (used in the present study), to live streaming (made available in 2016). In order to start the feasibility study, three complete listening kits comprised of an iPod loaded with the experimental programme, a digital amplifier, cable, and bone conduction headphones were secured.

For the full study, 40 iPods were loaded with Programme A and Programme B, indicated with an A or B sticker on the back. The headphones were Sennheiser bone conduction eH350 model with an ABT digital bone conduction amplifier, which operates with 2 AA batteries. The company recommends using bone conduction headphones for their TLP Spectrum edition when used with ASC children, children with brain injury, and other sensitive listeners.

Listening with air/bone conduction headphones is considered a more natural experience, as environmental sounds and voices are normally heard via air conduction, while one's own voice is heard via bone conduction. The headphones have been fitted with a small, round transducer, which is secured to the headphones and sits at the top of the head. The transducer is connected to a digital amplifier that amplifies the sound, which travels through the bones in the skull to the inner ear. Although the company recommends their use for ASC children, no studies have explored whether there are any measurable improvements in results for ASC children.

3.45 Study procedures

The intervention took place in the home and consisted of five daily sessions with two days off per week (usually the weekend when the family routine changes) for 20 weeks. Listening could be in two separate 15 minute modules per day or the two modules could be listened to sequentially for a total of 30 minutes. Timing was determined by the ability of the child to tolerate listening with headphones and the family schedule. The creators of the programme established this listening protocol to encourage compliance within diverse family settings and situations.

For the purpose of this study, if a child missed one or two listening sessions, the listening time could be made up on the weekend. This would ensure that all children in the study in both listening groups listened for the same amount of time over the 20 week period. A Listening Diary was created as part of the Guidelines booklet (Appendix H) and given to each family to track compliance. Each 15 minute listening segment is noted from numbers 1 to 200, and boxes were ticked to indicate that the child had listened to each segment. A space was provided for notes that might include unusual events during the week that upset the child's routine. Parents were asked to return the diary to the investigator at the end of the study.

A naturalistic environment such as a family home does not allow the possibility of controlling all elements. In order to establish a somewhat comparable environment and to aid in establishing a routine, parents were asked to find a place in the home that was quiet and apart from other family activities that might be distracting, and to stay with the same daily time(s) for the entire length of the study. Suggested times were before and after school or at bedtime.

A child between the ages of 4 and 8 was not expected to simply sit and listen without any activity, but the child should be actively listening to the music rather than engaging in a cognitive or other mentally distracting activity. The supervising parent was asked to create an activity box that would include the listening equipment and various small toys and craft items that their child enjoys. A list of approved activities was given in the Guidelines and Instructions booklet (Appendix H). Parents were asked to set a timer so they would know when the modules were finished, as a child should listen to a total of 30 minutes in one day. The passive control group were not required to engage in any daily activity.

An exception to daily listening was noted if a child had developed an ear infection and his or her ears subsequently become plugged, as listening might become uncomfortable. Parents were advised their child should be taken to the family doctor and return to regular listening when their ears were clear again, making a note of the details in the Listening Diary.

3.5 Proposed Analyses

The study was designed as a randomized controlled trial with a partial double blind design with two listening groups and a control group with no intervention. It was hypothesized that the level of improvement would be greatest for trial participants in the experimental group, as compared to the active or passive control groups in the three domains of Communication, Social Abilities, and Behaviours. It was also hypothesized that the level of improvement would be greater for trial participants in the active control group compared to the passive control group but less than participants in the experimental group.

Primary analysis first compared descriptive characteristics of the three groups to determine if they were comparable at baseline. SPSS repeated measures Analyses of Variance, ANOVAs, were used to determine the statistical significance first between the three groups in each domain, and then a second analysis to determine differences between the experimental and passive control groups over time in the three selected domains.

Analysing each domain separately at baseline and 20 weeks was undertaken to clarify what factors are most likely to change with the intervention, as measures used and factors assessed have been inconsistent in past studies. Identifying changes most likely to occur by domain may also suggest characteristics of children most likely to respond to the intervention. All children are not expected to respond in the same manner, as each child may have a different reaction to sound, which may interfere with abilities and behaviours in a different way.

3.6 Feasibility Study

A feasibility study was determined to be important for the present study. Using the definition of the National Institute for Health Research, Evaluation, Trials, and Studies Coordinating Centre (NETSCC), a feasibility study is conducted before a full or main study and the goal is to gather information that can be used to provide better estimates for details meant to improve the design of the full study. The feasibility study will also allow the investigator to become familiar with the autism community in the UK and determine the best way to advertise, enrol participants, and work with parents.

The music listening programme being used in the study has been available commercially in various editions for over 15 years, so daily listening times, safety issues, and general protocols, had already been established. It is commonly used in the home. Testing elements such as those related to eligibility for the study, ease of getting a child started with listening through headphones, equipment use, parental accountability, completing assessments, and others would likely improve the level of compliance as the study relies on parents to implement and maintain daily listening as well as complete assessments. Testing recruitment materials, methods, and guidelines for helping their child adjust to the listening protocol, would help in estimating the required timeline.

The creators of the programme do not allow families to purchase it directly, but must do so from a therapist who has been trained by the supplier. The therapist determines if the client might benefit, and may recommend the programme before or after implementing their own therapeutic programmes. In this case, the trial is open to any interested family meeting the requirements and a family will not have the expertise of a trained OT, speech language therapist, or educator to help the family begin or help to oversee the listening protocol. This may be considered a strength of the study, as a more pure means of testing the programme alone. It also means testing the written guidelines is especially important before the full study begins.

A parent-directed intervention has many advantages for a family, yet in daily life unexpected situations can interfere with routines. Although guidelines were given, a highly controlled trial in a real world family home setting is unlikely, as protocols and schedules cannot always be followed in spite of best efforts. This may provide unexpected challenges to the investigator, but the benefit of a naturalistic setting is learning if the intervention will still create change under actual, rather than ideal conditions.

3.61 Components of the feasibility study

A feasibility study was therefore undertaken to test materials and procedures in advance of the full randomized, double-blind, controlled trial. The components to examine in the study were:

- recruitment materials, methods and parental response
- evaluation of study guidelines and instructions
- ease of equipment use by parent and child

- compliance to protocols
- extent of necessary interaction with parent
- completion of online and paper assessments
- parental response to study
- establishment of an overall time line

3.62 Recruitment materials, methods and response

Three listening kits were secured on loan from the supplier in order to begin. The kits included three bone conduction headphones with cables and amplifiers from their UK representative and three iPods containing the experimental programme sent from the company's US headquarters. It was determined that three families should be adequate to test components of the study.

Personal networking yielded names of three families interested in participating in the feasibility study. The first family immediately signed and returned the two forms. The second family was involved in another intervention and did not qualify but asked to be contacted for the full study, the third did not reply after the inclusion criteria were restated in an email. This pattern suggested that even if families expressed an interest, it was possible a smaller number might be eligible and commit to the requirements and timeline of the study. Recruitment might take more effort and a longer timeline than anticipated.

Listening equipment and instructions were mailed to the first family who lived on the west coast of Scotland. Assessments were quickly returned and the parent began to work with her child. The child was on the severe end of the spectrum and the parent struggled to get him to wear headphones. He eventually managed 30 minutes one day, refusing to remove them at 15 minutes, then refused to wear them at all on subsequent days. A number of suggestions were given via email in addition to those in the instruction booklet for distracting and encouraging him to wear the headphones. After three weeks of attempting compliance, the parent returned the equipment saying that for the benefit of the study, she felt it would simply take too long to get her son started, so she was withdrawing from the study.

Meanwhile two other parents had enrolled who were located in Edinburgh. These parents were recruited by networking through a charity providing services for ASC families. The inquiring parents were directed to the website to be sure they understood the requirements for the study. They each then completed and returned the Parental Permission and Loan of Equipment form (Appendix C).

When arranging to meet and deliver the equipment, it was learned that the mothers knew each other. They were both very proactive and together, moderated an online ASC support group for the local area. Learning of the presence of online support groups in communities all over the UK suggested an opportunity to recruit by going directly to ASC parents using the Internet.

3.63 Evaluation of instructions and equipment use

A child on the autistic spectrum may have sensitivities to touch and sound, as well as behavioural issues, so the initial challenge for some parents is simply to ensure their child will tolerate wearing headphones for at least 15 minutes, twice a day. This may take a week or two, and occasionally, much longer. Assistance in wearing headphones and starting listening is ordinarily given by the therapist who oversees the programme. Often the therapist has already been working with the child. It was not within the scope of this study to provide personal assistance with these issues, so recruitment literature notes that a child must be able to wear headphones.

For the study, this preliminary assistance was undertaken with written Guidelines and Instructions (Appendix H), which included a Listening Diary to help parents track the two daily 15 minute segments for the 20 week listening period of the study. Both parents took at least four weeks to read the guidelines and begin the listening protocol.

Bone conduction headphones have an amplifier and cables, which require a brief level of additional learning. The guidelines gave written instructions for using the listening equipment and one parent reported referring to the written instructions when a cable became disconnected from the amplifier. An instructional video for the bone conduction audio system was posted on the study website in the section for Participants Only, with parents told to use the password “spectrum.” The video, also on YouTube, (“ABT Bone Conduction” 2017) was approximately eight minutes and created by the company for those who might prefer an audiovisual explanation rather than a written one. The company information was removed from the beginning and ending of the video for the website. Neither parent reported any difficulties learning to use the listening equipment.

The iPods containing the two listening programmes did not have any company logo or identifying information. It should be noted that the digital amplifier did contain “ABT”, the company logo (but not the full name), which appeared briefly when the device was turned on and this could not be changed. It is also possible the logo might be interpreted as the company who created the amplifier.

Four boxes containing 10 AA batteries, a total of 40 batteries, were provided for each family to ensure that the need to replace batteries in the amplifier would not interfere with adhering to the listening protocol of 20 weeks. Both parents reported that usage at about 6 weeks into the study suggested 40 batteries would be adequate for the 20 week listening protocol. The parents were provided with a USB wall plug charger as well. One parent said she didn’t need the plug as they had several at home, and returned it. After this, each participating parent was asked if they needed a wall plug charger in order to cut purchasing and mailing costs.

3.64 Completion of assessments

Cambridge University's Autism Spectrum Quotient: Children's Version (AQ-Child) measures the degree to which a child has traits that are typical of ASC and their severity. The Autism Treatment Evaluation Checklist (ATEC) assesses abilities, behaviours and health issues specific to ASC individuals, to help parents determine if their child might benefit from an intervention. The purpose of the Autism Parenting Stress Index (APSI) is to provide information on how well a parent is coping. These three assessments, the AQ-Child, the ATEC, and the APSI were recreated first on paper to maintain uniformity, then recreated online at BOS Bristol Online Survey. The fourth assessment, the Vineland Adaptive Behaviour Scales, Vineland II, is a paper booklet, which was purchased and a copy was given to the participants along with the equipment. Both parents completed the four assessments and returned them without difficulty. After the parent reported their child had begun daily listening, emails were sent each Friday with a link for the online ATEC, chosen for weekly reporting and for the follow-up, but completing it weekly was difficult for one of the parents.

In an email at week 13, the first parent reported that she didn't feel the online survey (ATEC) was reflecting the changes she was seeing in her son. He was asking more and more questions, asking her to name objects and explain things he had not noticed before. She commented that her son had asked her about autism for the first time and had understood a simple explanation. At week 17 she had seen more improvements with increased eye contact and improved fine motor skill using a pencil. He used to draw the same picture over and over but now was prolific in drawing different pictures. He was still hyperactive, and one email reported he had been shouting a lot, using a very loud voice, yet was still more aware of feelings of others and asking lots of questions.

3.65 Compliance to protocols

The study ran over the Christmas holidays, which is often a difficult time for children on the autistic spectrum when routines are interrupted. After the holidays, meetings were arranged with both parents about six weeks into their listening schedules. One child's grandmother had fallen ill during her visit over the Christmas holidays and needed extensive care. The parent had no time to maintain compliance and the child had stopped listening for several weeks.

A second break in the listening protocol occurred for the first parent as the older child became ill and was hospitalized and the parent was unable to manage listening sessions for the younger child in the study. Getting back to the listening schedule was difficult and the parent reported in an email that her child was "twitchy and hyperactive," so it was difficult for him to keep the headphones on. He was able to manage one 15 minute session a day at first and then build up to two sessions within a week.

The first parent reported that compliance was difficult in the beginning. The child often complained that his ears were sweaty and he wanted to remove the headphones. This happened because he had sports activities prior to his listening session. The breaks in listening due to family illnesses meant having to establish a routine again. The mother found eventually that first thing in the morning, after toileting, was the best time for listening. Her son often woke up feeling anxious and this routine had a very calming effect for him. He knew he would get back into bed and listen, and began to enjoy the experience, which helped him to start the day more relaxed.

The second parent reported her child had a poor immune system and was often ill. Since the fall term in a new mainstream school, the child had been extremely anxious, had difficulty sleeping through the night, and was having difficulty coping. In conversation, the mother explained they were attempting listening for 30 minutes late in the day, which was given as an option in the guidelines. Even at 6 weeks into the protocol, they had still not established a specific daily listening routine, as the child's sleeping habits were so erratic. Two 15 minute sessions were strongly recommended, with one before breakfast and one after school. A few weeks later in an email, the parent reported she was managing the two separate listening times on most days, that sleep was easier for her child, school anxiety had lessened, she had moved up another reading level, and was eating better.

At 20 weeks, the second parent reported she was never able to maintain a regular listening routine. The child complained about listening and often asked why she had to do it. The mother struggled and often spent an extra half hour just getting her to listen. Because of this, she reported that she would not be willing to continue any longer than 20 weeks. However, her daughter did experience positive changes, particularly in her ability to tolerate noise, and she said that looking back, she was very glad to have had the opportunity to take part in the study.

Email prompts were necessary to remind both parents to complete the follow-up assessments. One parent completed the 30 week ATEC follow-up showing that improvements were continuing; and both completed the 40 week ATEC follow-up assessment with further improvements noted at the end of 40 weeks.

3.66 Follow up with parents

Meetings with each parent separately at approximately six to eight weeks into the listening timeline were arranged. The first parent reported she had already seen positive changes in her son who had spontaneously shouted "Goodbye Mum" for the first time when she left for work and he had played with other boys at his school without being directed to do so, another first. He was beginning to notice more things and ask more questions.

The first parent also reported a strange experience as her child became very upset when she told him she was unable to attend his school nativity. His father would attend, but she was unable to leave work. Normally he would not be at all aware of this. Now he was very upset and said he wanted her to go because he loved her so very much. This was very strange for the mother, as her son had never shown much emotion to others, or to her. As a child begins to notice and become aware of more things, the initial result may be positive or upsetting until the child becomes used to and/or understands the new awareness.

The second parent was very grateful for the meeting to discuss the difficulty she was having, getting her child to settle down and listen. Her child's sleeping habits were so erratic, she didn't want to awaken her in the morning for a listening session before school. However, trying a morning listening session was recommended to see if it might help her child cope better in school.

It became clear from these two cases that a parent needs to be motivated to adhere to the 20-week protocol, and adherence is easier when results were observed. Each parent appreciated having an opportunity to discuss her concerns in person as it helped to understand changes in her child and feel comfortable about continuing the programme. In spite of difficulties establishing a reliable routine, both parents were very motivated to continue.

Second interviews were arranged after each parent had completed the 20-week listening protocol. The first mother reported that she had been anxious about her son having one morning in a mainstream school, but after the listening study felt that he would be able to manage with an aide. The special school he attended had also noted changes and needed to find new, more challenging materials for him. The teachers reported he had shown increased sociability and awareness, and was asking many questions, such as what was a rare species. The mother said he had stopped his odd behaviours including "Tourette's like noises" and twitching and her son was "quite a different boy now." She was especially grateful to have been able to participate.

It took several weeks before an appointment for an interview with the second parent could be made. The mother then reported if she had been able to complete the assessments at that time (at 27 weeks rather than at 20 weeks), she would have been able to make quite a different report. The family had been able to do many activities that previously had been impossible, as their child previously could not tolerate noise or social situations, often for more than 10 minutes. The mother reported they had now been able to attend and sit through a music event, enjoy an outdoor festival with crowds and noise, and that their child was now anxious to attend family birthday parties. She reported her child was less sensitive to noise, was more verbal when there was loud noise, was less stressed at noisy events, and these changes have improved the family's quality of life.

3.87 Changes made for full study

Recruitment, arranging to meet and deliver the equipment, the participating parent reading all the instructions, and the child finally starting daily listening took approximately two months. This was longer than expected, but family challenges played a role in the delays, again emphasizing the real world conditions of the study. Families with a child or children on the autistic spectrum have greater challenges than the normal family, and one of the participating families also had an older son with ASC. The influence of home conditions was also reflected in the 20-week protocol for the listening portion of the study. Both parents took from two to four additional weeks to complete the requested 20 weeks of listening.

From experiences and feedback in the feasibility study, elements related to recruitment, listening equipment, completion of assessments, guidelines for listening, and required timeline were modified for the full study. Although a poster and brochure had been created that could be distributed in Edinburgh, it was decided to begin recruitment online first through ASC parent support groups. As one parent did not need a rechargeable wall plug, it was determined to ask parents in advance if they needed the wall plug, and only include one in the listening kit if needed. Parents were also asked if they would like a paper diary or prefer just the digital diary. Both changes were implemented to reduce equipment purchase and mailing costs.

To increase compliance and accountability, a reminder with a box to tick plus a link for completing the weekly online assessment was added to the listening diary. A separate diary was created for the passive control group using the same system to track the completion of baseline and post assessments and the weekly online assessment. Guidelines were edited to strongly encourage all parents to establish the routine of two separate 15 minute sessions, one in the morning and one after school, rather than one 30 minute session, although this remained an option.

The parents accepted the process for the feasibility study, but daily life circumstances made it difficult to follow all the guidelines, and it was sometimes an effort to complete assessments. From the parental response, it was clear that both initial and continued support should be offered, especially in getting their child started listening; this could be done with suggestions and encouragement in personalized emails as needed.

The period between enrolment in the study, receiving listening equipment and actually starting listening had taken two months for both families living in Edinburgh. If a child did not easily adapt to wearing headphones, starting the study might take additional time. After starting, family issues had necessitated listening breaks, which extended the

20-week listening protocol. It had been anticipated that the majority of participants would be from Edinburgh. As the first family to start the study was not in the city, this required purchasing mailing supplies, packing equipment, and shipping costs. It was acknowledged that if families were outside the city, mailing equipment and assessments to each family would add to the time and effort. Therefore the estimated timeline was revised to add additional time for delivery of listening equipment, getting started listening, and completing the listening protocol.

Even if inquiries exceeded 60 families, more extensive recruitment would likely be required to actually enrol 60 families and might take several months. Given the longer study timeline and prospective recruitment challenges, it was determined that recruitment efforts for the full study should begin before the feasibility study had concluded. While necessary from a practical view, this would also mean that follow-up compliance, and return of equipment efforts could not be fully evaluated before starting the full study.

4.0 Results of the RCT

This first RCT will assess several aspects of the experimental programme, to determine if data supports the preliminary trends and anecdotal evidence in studies cited in the literature review. The partial double blind design of two listening groups will test the filtered music stimulus as compared to an unfiltered stimulus, and the third group will act as a control for the intervention. The primary hypothesis states that when the 20 week protocol is followed, a significant improvement in scores will be seen in the domains of Communication, Social Abilities, and/or Behaviours for children in the experimental group as compared to the active or passive control groups. Three way repeated measures ANOVAs were run for these three ATEC domains using scores at baseline, 20 weeks and at the 40 week follow-up. It was hypothesized that the experimental group would show greater change than the passive control group and mean scores for the active control group would fall somewhere between these two group scores. To further evaluate results, two way repeated measures ANOVAs were run to compare the experimental and passive control groups. Follow-up data was obtained at 40 weeks to also determine if any changes had maintained after listening had ceased for 20 weeks. Improvement is shown by a decrease in scores over time for all measures.

Commented [SM4]: Please stick to your original primary hypothesis – its ok to be specific about the dependent variables or intended outcomes, but don't lose the elegance of your design – you had a three way comparison for a reason, you are both controlling for the behavioral intervention as well as the music stimulus!

It is also good to repeat your full set of hypotheses here

Secondary analyses were conducted to determine if there was a change in severity of aautistic symptoms at 20 weeks as measured by the AQ Child, and if parental stress levels, as measured by the Autism Parental Stress Index, had changed after using the intervention. Analyses of co-variance, ANCOVAs were run to control for baseline score, age, parental stress and severity of symptoms. Case summaries were examined for information on best responders and to examine patterns of response for the three groups.

4.1 Data Collection

Recruitment took place over a ten month period and a flow chart (Figure 1) illustrates that 152 families, 8 with twins or siblings with ASC for a total of 160 children, asked to take part. Sixty-one families signed Permission to Participate and Loan of Equipment forms including two who signed forms for each twin, making a total of 63 children in the full study. The long term nature of the study, not being able to be engaged in other interventions, and the possibility of being in a control group without any intervention were issues for some parents and drop outs are noted on the recruitment chart (Figure 1).

Figure 1 Recruitment Flow Chart

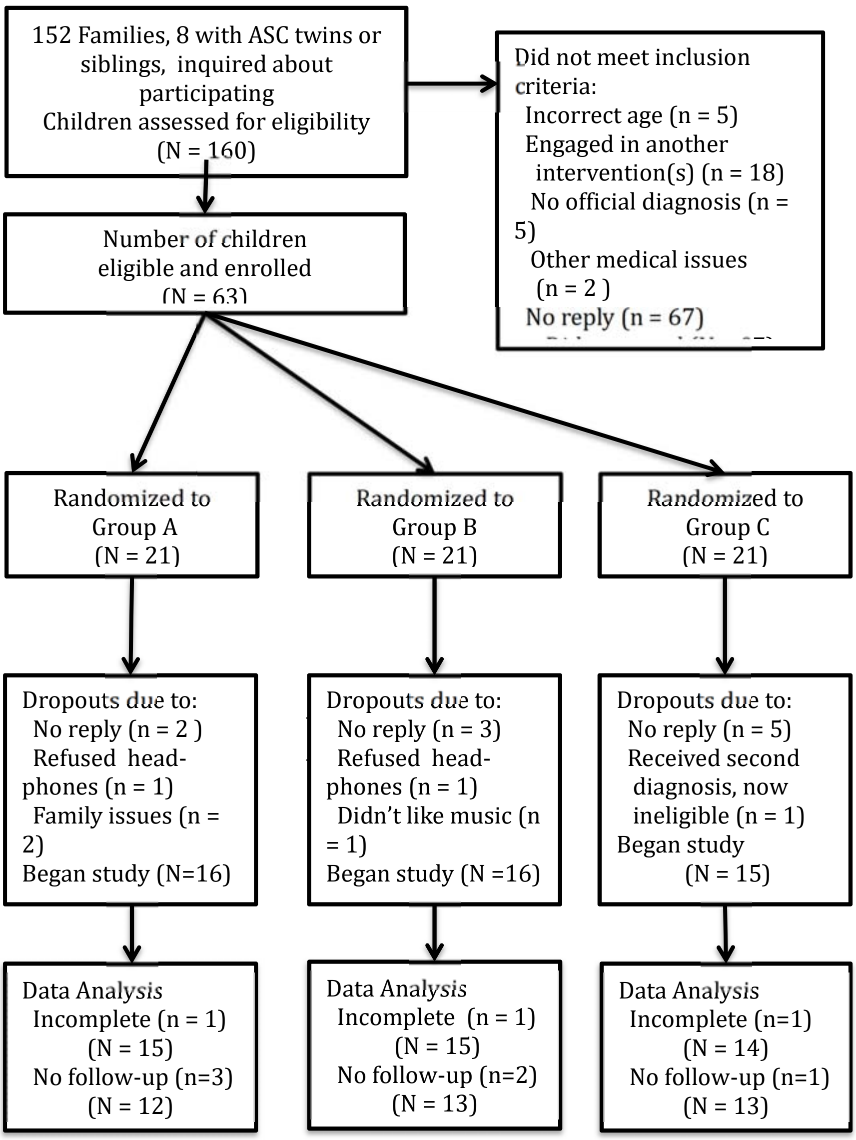

Figure 1. Flow chart showing initial recruitment and retention rates for the study.

4.2 Descriptive Statistics

Tests of normality, histograms and boxplots all showed that scores were reasonably normal in distribution for the sample, for all three groups. Mean and trimmed mean values were similar, indicating outliers were not affecting calculations. Ages were distributed evenly between all three groups as shown in Table 1, with the majority of participants falling in the age range of 5 to 7 years. Gender was skewed in favour of males as expected.

Based on boxplots for the three groups, one outlier was seen in the experimental group. The outlier of 141 was only two points greater than the second highest score within the three groups and could be expected in a random sample of children on the autism spectrum. A Shapiro-Wilk's test of normality showed that all numbers were significantly above .05, indicating data were normally distributed for each group. Homogeneity of variances as assessed with the Levene statistic (.172), indicated equality of variances was not significant (p = .842).

Numbers as shown in Tables 1, 2, and 3 include intention to treat. A confidence level of 95% is used for all statistical tests.

Table 1

ATEC: Gender.

Baseline SPSS Descriptive Statistics for gender of participants.

Gender	Number (%)
Males	46 (88.5%)
Females	6 (11.5%)

Table 2

ATEC: Age.

Baseline SPSS Descriptive Statistics for children in the autism listening study for age.

Number of children for each age in each group: Experimental, Active Control, and Passive Control.

	Age in Years					
Group	4	5	6	7	8	9/10
1. Experimental	3	3	3	5	1	0
2. Active Control	1	5	4	3	1	1
3. Passive Control	0	4	5	3	1	1
Total	4	12	12	11	3	2

Table 3

ATEC:Baseline mean scores for three domains,.

SPSS Descriptive Statistics for Communication, Social Abilities, and Behaviours, showing MEAN and (SD)

Scores at Baseline based on group numbers. N includes intention to treat.

Group	N	Communication	Social Abilities	Behaviours
1. Experimental	18	10.244 6.022)	12.94 (4.929)	25.11 (9.634)
2. Active Control	18	10.89 (5.999)	13.89 (7.070)	22.11 (11.752)
3. Passive Control	16	10.31 (6.096)	14.81 (6.0026)	25.38 (9.701)

4.3 ATEC: Communication

A three way repeated measures ANOVA was run to determine the effect on three different groups over time for the three domains, Communication, Social Abilities, and Behaviours. The first analysis was run for Communication. There was one outlier in the data for the active control group as assessed by one 1.5 box lengths from the top of the box and the same case outlier in both the pre and post data for the passive control group, assessed as a value greater than 3 box-lengths from the edge of the box. All outliers are within the normal range for the autism spectrum and it was not considered necessary to transform the data. Communication scores were not normally distributed as the passive control group at baseline was assessed by the Shapiro Wilk's test of normality $p = .01$. All other values were $p = >.05$. Mauchley's test of sphericity indicated that the assumption of sphericity was met for the three way interaction, p = .490. There was not a statistically significant three-way interaction between the three groups over time, $F(2,35) = .429$, $p = .654$, partial $\eta^2 = .024$.

Pairwise comparisons show the mean difference between baseline and 20 weeks was 1.278 (.400 to 2.155) $p = .005$ with Bonferroni adjustment for multiple comparisons. There was not a statistically significant difference between groups from baseline to 20 weeks or at the follow-up at 40 weeks. Post Hoc comparisons showed there was a statistically significant difference over time between baseline and 40 weeks, $p = .0005$. Therefore main effects were run. Individual repeated measures ANOVAs for the passive control group showed a significant effort of time, $F(2,11) = 6.595$, $p = .012$, partial $\eta^2 = .553$. The experimental group did not show a significant effect of time, $F(2,10) = 3.997$, $p = .053$ partial $\eta^2 = .444$.

Table 4

ATEC: Communication

Three Way Repeated Measures ANOVA, mean score comparisons between the Experimental group and the Active and Passive Control grousp at baseline, 20 and 40 weeks with Bonferroni adjustments for multiple comparisons.

		Baseline	20 Weeks	40 Weeks
Group	N	Mean (SD)	Mean (SD)	Mean (SD)
Experimental	12	10.08 (5.401)	8.33 (5.123)	8.25 (6.254)
Active Control	13	11.23 (6.193)	10.15 (6.243	9.54 (6.118)
Passive Control	13	9.31 (5.218)	8.77 (5.747)	6.85 (6.162)

95% Confidence Interval, Error (within groups = 28)

4.4 ATEC: Social Abilities.

There was one outlier in the experimental and control groups and two outliers in the active control group for the domain Social Abilities, with two cases assessed as a value greater then 3 box lengths from the edge of the box. All were in the normal range for children across the spectrum, and it was not considered necessary to transform the data. Social Abilities scores were not normally distributed as the passive control group at baseline was assessed by the Shapiro Wilk's test of normality p = .01. All other values were p = >.05. Mauchley's test of sphericity indicated that the assumption of sphericity was met for time, p = .435.

There was not a statistically significant three-way interaction between the three groups over time, p = .371, partial η^2 = .057. Therefore main effects were run. The main effect of time showed a statistically significant difference in Social Abilities scores between time points, F(2,68) = 4.494, p = .015, partial η^2 = .117. Pairwise comparisons show a significant difference between baseline and 40 weeks only, p = .044 with a mean difference of 2.015 (.045 to 3.9850).

To further confirm the differences between the groups, a two-way repeated measures ANOVA was run to compare the effect of two different groups over time, to determine if improvement had occurred in the experimental group as compared to the passive control group. For the ATEC, improvement is shown by a decrease in scores. Scores were normally distributed except at the beginning of the trial (p = .022) as assessed by the Shapiro-Wilk test of normality.

In the domain Social Abilities, there was a significant two-way interaction between time and group F(1,28) = 8.129, p = .008, η^2= .225. Simple main effects were run and showed the average mean difference at the beginning of the trial for the experimental group was 3.562 (95% CI, -7.479 to .354) lower than the passive control group and the difference was not significant, p = .073. Data for mean and SD of Social Abilities are shown in Table 5.

The effect of time from baseline to 20 weeks showed a statistically significant difference in scores over time, $F(1,28) = 4.573$, $p = .041$, $\eta^2 = .140$. Simple main effects for the experimental group showed a significant difference from baseline to 20 weeks of $p = .008$, $\eta^2 = .225$, but the passive control group did not show a significant difference, $p = .183$, $\eta^2 = .041$, showing a slight increase in scores or worsening.

There was a significant two-way interaction between time and group $F(1,28) = 8.129$, $p = .008$, $\eta^2 = .225$. Simple main effects were run and showed the average mean difference at the beginning of the trial for the experimental group was 3.562 (95% CI, -7.479 to .354) lower than the passive control group and the difference was not significant, p = .073. Data for mean and SD of Social Abilities at baseline and 20 weeks are shown in Table 5.

Table 5

ATEC: Social Abilities. SPSS Two Way Repeated Measures ANOVA, Descriptive Statistics and Analyses between the Experimental group and the Passive Control group, from baseline to 20 weeks..

		Baseline		20 Weeks					
Group	N	Mean	*SD*	Mean	*SD*	*Df*	*F*	p	η^2
Experimental	16	10.25	5.471	8.31	4.600	1	16.367	.0005	.369
Passive Control	14	9.29	5.014	8.86	5.531	1	6.668	.015	.192

Note: 95% Confidence Interval, Error (within groups = 28), Bonferroni adjustment for multiple comparisons.

4.5 ATEC: Behaviours

There were two outliers, one in the active and one in the passive control groups, with both assessed as a value greater then 1.5 box lengths from the edge of the box. All were in the normal range for children across the autistic spectrum, and it was not considered necessary to transform the data. Behaviour scores were normally distributed at baseline and 20 weeks for all groups as assessed by the Shapiro Wilk's test of normality *p* = >.05. However, scores at 40 weeks were not normally distributed for the active (*p* = .01) and passive (*p* = .025) control groups. Mauchley's test of sphericity indicated that the assumption of sphericity was not met for time, $x2(2) = 0.$ $p = .001$.

There was a statistically significant three-way interaction between the three groups over time using Wilk's Lsmbda, p = .033, partial $\eta^2 = .141$. Therefore simple main effects were run. As sphericity was not met, Greenhouse & Geisser (1959) was used to correct the three-way repeated measures ANOVA. The scores for behaviours were not statistically significantly different between groups F(,2.979, 52.133), = 2.561, p = .065, . partial $\eta^2 = .128$.

To further confirm the differences between the groups, a two-way repeated measures ANOVA was run to compare the effects between two different groups over time, to determine if improvement had occurred in the experimental group as compared to the passive control group. One outlier was noted, showing a studentized residual value of 3.05. It was determined not severe enough to warrant transformation. Scores were normally distributed except for the passive control group at the end of the trial (*p* = .025) as assessed by the Shapiro-Wilk test of normality.

In the domain Behaviours, there was a significant two-way interaction between time and group $F(1,28) = 6.668$, $p = .015$, $\eta^2 = .192$. Simple main effects showed the average mean difference at the beginning of the trial for the experimental group was 4.187 (95% CI, -10.359 to 1.984) lower than the passive control group, a difference that was not significant, $p = .175$.

The effect of time from baseline to 20 weeks showed a statistically significant difference in scores, $F(1,28) = 16.367$, $p = .0005$, $\eta^2 = .369$. Simple main effects for the experimental group showed a significant difference from baseline to 20 weeks of $p = .008$, partial η^2= .225, but the passive control group did not show a significant difference over time, p = .183, partial η^2= .041.

Table 6

ATEC: Behaviours.

SPSS Two Way Repeated Measures ANOVA, descriptive statistics and analysis between the Experimental group and Passive Control group with Bonferroni adjustment for multiple comparisons.

		Baseline		20 Weeks					
Group	N	Mean	SD	Mean	SD	Df	F	*p*	η^2
Experimental	16	25.81	10.021	14.81	4.736	1	16.367	.0005	.369
Passive Control	14	25.71	10.344	23.29	11.479	1	6.668	.015	.192

Note: 95% Confidence Interval, Error (within groups = 28), and Bonferroni adjustment for multiple comparisons.

A second research question concerning the experimental programme was posed to determine if filtering and modifications to the music might be associated with change or if listening to similar unfiltered music using the same protocols would create the same effect. Data was transformed by computing the difference between baseline and 20 weeks and change scores were created for each individual, then a mean change score for each group and domain. The active control group was hypothesized to have mean change scores greater than the passive control group but less than the experimental group. A one way ANOVA was run for each domain to compare the mean difference for each of the three groups and results are shown in Table 7. The mean change scores for the active control group fell between the experimental group and the passive control group, for each domain, as hypothesized. A research question was also asked, is there a significant difference in scores between the active and passive control groups?

Table 7

ATEC: Mean Differencee for Group Scores in Three Domains

Findings of a one way ANOVA showing mean change between scores at baseline and 20 weeks for the domains Communication, Social Abilities, and Behaviour, for the Experimental, Active Control, and Passive Control groups.

	Communication	Social Abilities	Behaviour
Group	Mean Change	Mean Change	Mean Change
Experimental	1.9375	2.5000	11.0000
Active Control	1.4667	1.5333	5.3333
Passive Control	0.4286	-0.5000	2.4286

To further explore the differences between the active and passive control groups, and answer the research question, two way repeated measures ANOVAs were run. For the domain Communication, there was not a statistically significant difference between the two groups, $F(1,27) = .896$, $p= .352$, partial $\eta^2 = .032$. For the domain Social Abilities, there was not a statistically significant difference between the two groups, $F(1,27) = 1.212$, $p= .281$, partial $\eta^2 = .043$. And for the domain Behaviours, there was not a statistically significant difference between the two control groups, $F(1,27) = .824$, $p = .372$, partial $\eta^2 = .030$.

To answer the third question regarding the experimental listening programme, if the effect would change or maintain with no listening, a three way repeated measures ANOVA was run for the experimental group for each domain to determine if changes maintained after listening ended over an additional 20 weeks without intervention. Change was largely maintained for all three domains, (Table 8).

Table 8

ATEC: Mean Scores by Domain for the Experimental Group through Follow-up.

N = 12. Three Way Repeated Measures ANOVA at Baseline, 20 weeks, and 40 weeks for the Experimental group, 95% Confidence Interval, with Bonferroni adjustments for multiple comparisons.

	Baseline		20 Weeks		40 weeks	
Domain	Mean	SD	Mean	SD	Mean	SD
Communication	10.08	5.401	8.33	5.123	8.25	6.254
Social Abilities	13.08	4.522	9.50	4.011	10.17	4.988
Behaviours	28.08	9.405	15.17	4.345	18.00	6.578

4.6 Secondary Analyses

Two additional assessments were used to answer research questions related to severity of symptoms and to parental stress levels. Severity of symptoms vary widely across the autism spectrum. As severity may impact outcomes, it is important to be certain groups are equal in their range of severity. The Autism Quotient (AQ-Child) was selected to determine severity of symptoms at baseline and after 20 weeks.

4.61 Autism Quotient (AQ Child)

AQ-Child scores indicate severity of traits associated with ASC ranging from 0 to 150 with the ASC cut-off starting at 76 (mild), and extending to 150 (severe). A reduction in the total score indicates a reduction in severity of symptoms. The AQ-Child was used to first determine equivalence of severity of symptoms between the three groups at baseline. Descriptive statistics were produced by a two-way repeated measures ANOVA. A review of the data showed the Levene statistic (.361) indicated homogeneity of variances. A Shapiro-Wilk test showed $p > .05$, indicating that standardized residuals for the groups were normally distributed.

The intervention is theorized to reduce the severity of symptoms associated with auditory sensitivities and some of these are described in the AQ Child. Therefore a two way repeated measures ANOVA was run to determine if there might be a reduction in severity of symptoms at 20 weeks for the experimental group as compared to the passive control group.

There was not a statistically significant interaction over time, $F(1,27) = 2.647$, $p = .115$, $\eta^2 = .089$, or between the two groups over time, $F(1,27) = .718$, $p = .404$, $\eta^2 = .026$. Main effects were run showing that the mean difference between the two time points, 3.726 (95% CI, -.973 to 8.425), $p = .115$, and between the experimental and passive control groups $F(1,27) = 6.063$, $p = .020$, partial $\eta^2 = .183$. To determine the effect of the difference, an ANCOVA using baseline AQ scores as a covariate was run and did not show a statistically significant difference ($p = .112$) between the two groups.

Table 9

APSI and AQ Child: Baseline Mean Scores for Three Groups

One Way ANOVA for APSI, and for AQ Child, showing MEAN (SD) Scores at Baseline based on group numbers that include intention to treat. Assessments are: Autism Quotient (AQ Child), and Autism Parental Stress Index (APSI).

Group	N	AQ Child	N	APSI
1. **Experimental**	16	98.56 (16.75)	16	22.06 (8.98)
2. **Active Control**	17	103.59 (18.99)	18	21.89 (8.80)
3. **Passive Control**	15	107.87 (17.17)	16	21.90 (8.39)

4.62 Autism Parental Stress Index (APSI)

The APSI is a type of assessment recommended for any treatment for ASC, to assess how in addition to finding if a treatment is effective, how implementing and maintaining the treatment may impact parents and families. APSI scores indicate stress levels on a total scale of 0 to 50, with higher scores indicating greater stress. A reduction in total scores indicates a reduction in stress levels. The APSI was used to answer the question, Will the use of the experimental programme for the required protocol reduce stress greater than no intervention in areas known to cause concern to an ASC family?

Descriptive statistics were produced by a two way repeated measures ANOVA and indicated there was one outlier at baseline that had a studentized residual value of 3.06. The Shapiro-Wilk test of normality indicated that at baseline the assumption of normality was met for the passive control (p = >.05), but not for the experimental group (p = .018). This violation of normality was not considered problematic and data was not transformed.

A two-way repeated measures ANOVA was run to determine the effect on stress levels on a parent whose child was in the experimental group as compared to a parent whose child was in the passive control group from baseline to 20 weeks. There was a significant two-way interaction between time and group, $F(1,27) = 7.18$, $p = .012$, $\eta^2 = .210$, showing a large effect size. Simple main effects were run showing that the mean score for the experimental group was 3.460 (95% CI, -9.148 to 2.229) less than the control group at the beginning of the trial, a difference that was not statistically significant F(1,27) =1.557, $p = .055$.

Results did not show a significant change over time for the two groups, $F(1,27) = 2.30$, $p = .141$, $\eta^2 = 079$. Main effects of time were run and showed a significant difference at 20 weeks for parental stress levels in the experimental group over time with a large effect size, $F(1,14) = 8.791$, $p = .010$, $\eta^2 = .386$. Parental stress levels in the passive control group did not show a significant change over time, $F(1,13) = .681$, $p = .424$, partial $\eta^2 = .050$.

4.63 ANCOVAs for Communication

To determine if any further differences might exist between the groups, Analyses of Co-variance (ANCOVAs) were conducted to determine the effects of baseline scores, severity of symptoms, age, and parent stress levels for each domain. For the ATEC Communication domain, assumptions were tested and there was a linear relationship between pre and post intervention for total scores for each intervention group as assessed by visual inspection of a scatterplot. There was homogeneity of regression slopes as the interaction term was not statistically significant $F(2,39) = 1.123$. $p = 336$. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variances, (p = .181). There were no outliers in the data, as assessed by visual inspection of ZRE scores and no cases with standardized residuals greater than + or -3 standard deviations. After adjustment for the pre-intervention mean scores for Communication, there was a statistically significant difference in post-intervention Communication scores between the groups, $F(3,40) = 6.728$, $p = .001$, partial $\eta^2 = .335$. Post hoc analysis was performed with a Bonferroni adjustment. Data are adjusted mean +or- standard error, unless otherwise stated. Change in scores for the domain Communication were not statistically significantly different between the experimental group compared to the passive control group at baseline, a mean difference of 1.705 (95% CI, -2.909 to 1.603), scores, $p = .297$.

ANCOVAs were also conducted to determine the effect of a control trial on the communication domain scores for an experimental and a passive control group at baseline after controlling for age, parental stress (APSI) and the severity of symptoms (AQ Child). There was a linear relationship between pre- and post-intervention scores for the communication domain for each group as assessed by visual inspection of a scatterplot. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variances, ($p = .156$).). There were no outliers in the data, as assessed by visual inspection of ZRE scores and no cases with standardized residuals greater than + or -3 standard deviations. Standardized residuals for the groups were normally distributed, as assessed by the Shapiro Wilk test (p = >.05). There was one outlier in the experimental group based on the standardized residual for the Communication domain at 20 weeks. However, the value is within the range seen in the passive control group and is not considered unusual. There was homoscedasticity, as assessed by visual inspection of the standardized residuals plotted against the predicted values. ATEC mean scores at 20 weeks for the experimental group were lower (8.60 + or - 4.61.), compared to the active control group (9.73 + or – 6.31) or the passive control group (8.86 + or – 5.53), respectively. After adjustment for pre-intervention communication scores, there was not a statistically significant difference between communication scores for the experimental group at baseline and at 20 weeks, F (2,39) = .259, p = .773, and no significant difference in communications scores at 20 weeks between the two groups when adjusted for age *F*(1,40) = 0.086 , *p* = .770. Communication mean difference scores were less in the experimental group (.653, -2.909 to 1.603) *p* = 1.000 at 20 weeks compared to the mean difference of the passive control group of (1.705, 4.229 to .819) *p* = .297 but were not significant.

There were no statistically significant differences in scores for the domain Communication after controlling for parental stress (APSI) *F* (1,39) = 6.355, *p* = .16, or for severity of symptoms as measured by the AQ-Child *F*(2/41 = .173, *p* = .842. Post Hoc analysis with Bonferroni adjustments did not show a significant difference between the three groups with the mean difference between the experimental and passive control group of 2.054, (-5.384 to 4.869, *p* = 1.000), and between the experimental and active control group of 1.133 (-6.171 to 3.904, *p* = 1.000).

4.64. ANCOVAs for Social Abilities

For the ATEC domain Social Abilities, there was homogeneity of regression slopes as the interaction term was not statistically significant F(2,39)= 1.478 , *p* = .241. Standardized residuals for the groups were normally distributed, as assessed by Shapiro Wilk's test *p* = >.05 There was homoscedasticity, as assessed by visual inspection of the standardized residuals plotted against the predicted values. There was homogeneity of variances, as assessed by Levene's test of homogeneity of variance (*p* = .572). There were no outliers in the data, as assessed by no cases with standardized residuals greater than + or – 3 standard deviations. After adjustment for pre-intervention scores for the ATEC domain for Social Abilities F(2,39) = 1.478, p = .241, there were no statistically significant influences from any of the covariables: severity of symptoms as assessed by the AQ-Child F (2,41) = 3.083. p = .057, age F(2,39) = 0.751, p = .479, or parental stress level as assessed by the APSI F(2,41) = 3.083, p = .057.

4.65 ANCOVAs for Behaviours

For the ATEC domain Behaviours, assumptions were tested and standardized residuals for the groups were normally distributed, as assessed by Shapiro-Wilk's test p = >.05. There was homoscedasticity as assessed by visual inspection of the standardized residuals plotted against the predicted values. Levene's test of Equality of error variances was not significant (p = .056). There were no outliers in the data, as assessed by no cases with standardized residuals greater than + or – 3 standard deviations. The assumption of homogeneity of variance was violated, as assessed by Levene's test for equality of error variances, p = .003. Mean scores at 20 weeks for the experimental group (14.055, 10.102 to 18.008) were lower than the active control group (18.307, 14.227 to 22.388) and the passive control group (22.608, 18.394 to 26.821), respectively. After adjustment for baseline scores for Behaviours, there was not a statistically significant difference at 20 weeks for scores between the experimental and passive control groups, F(2,39) = 3.212, p = .051, partial η^2 = .141.

After adjusting for parental stress, ATEC behaviours were significant at p = .042. Bonferroni adjustment for multiple comparisons, mean scores at 20 weeks for the experimental group (8.279, 16.379 to .180) were lower than mean scores for the passive control group (11.479, .877 to 17.892).

After adjustment for pre-intervention scores for the ATEC domain Behaviours F(2,39) = 1.478, $p = .241$, results were not significant, there were also no statistically significant influences from these covariables: severity of symptoms as assessed by the AQ-Child F (2,40) = 1.731. $p = .190$, partial $\eta^2 = .080$, or age $F(2,41) = .2741$, $p = .076$, partial $\eta^2 = .118$,. There was a significant correlation with the covariable parental stress level as assessed by the APSI $F(2,40) = 3.434$, $p = .042$, partial $\eta^2 = .147$.

4.66 Case Summaries

The Case Summaries procedure in SPSS was used to provide a visual examination of mean scores and differences from baseline to 20 weeks for individual cases in the three groups, for each of the three domains. Case summaries are shown in Appendix L. Two measures are used to indicate change: Standard Deviation (SD) to show statistical significance and Minimal Clinically Important Difference (MCID) to show change that is related to quality of life and while not statistically significant, can be discriminated by someone working with the child.

Minimal important difference (MID) was investigated by Norman, Sloan and Wyrwich (2003), who conducted a systematic review of 38 health studies and examined 62 effect sizes. The authors found in a number of health studies that the minimally important different (MID) estimates in all but 6 studies were close to one half a SD. The authors explored the consistency of various factors, such as effect size and longitudinal follow-up and determined that using half a standard deviation to define (MID) was an adequate threshold to discriminate change. MID scores are also referred to as minimal clinically important difference (MCID), and this term will be used in this thesis to indicate the differences that may be observed, to add significance for clinicians or educators who will be applying trial results (Jaeschke, Singer and Guyatt (1990). MCID scores are used along with Statistical Significance of at least one standard deviation in describing Case

Summaries to identify responders and were added to the case information in Parents' Comments (Table 15).

Table 10

SPSS Case Summaries Observations for ATEC Communication

Visual Examination of change scores for each case using Standard Deviation = 6, MCID = 3. Number of cases and range of scores deteriorated (MID <-3), improved but not significant (MCID =+3 to +5), significant change (SD = +6 and > 6). N = number of cases per range of scores (actual change scores showing number and range).

	N (Change)		N (Change)		N (Change)	1 SD	SD +
Group	< -3	%	>+3 to +5	MCID	+6 or >6	>1 SD	MCID
Experimental	0	0	4 (4,4,5,5)	25%	1 (9)	6%	31%
Active Control	0	0	2 (4,5)	13%	2 (7,9)	13%	26%
Passive Control	0	0	0	0	1 (6)	7%	7%

Table 11

SPSS Case Summaries Observations for ATEC Social Abilities.

Standard Deviation = 6, MCID = 3. Range of scores deteriorated (MCID <-3), improved but not significant (MCID =+3 to +5), significant change (SD = +6 and > 6). N = number of cases per range of scores (actual change scores showing number and range).

	N (Change)		N (Change)		N (Change)	1 SD /	SD +
Group	< -3	%	>+3 to +5	MID	+6 or >6	>1 SD	MID
Experimental	1 (-4)	6%	3 (5.5.5)	19%	5 (6,7,8,9,10)	31%	50%
Active Control	2 (-10,-9)	13%	3 (4,4,5)	20%	3 (7,10,11)	20%	40%
Passive Control	3 (-7,-6,-4)	21%	2 (4,**5**)	14%	0	0%	14%

Table 12

SPSS Case Summaries Observations for ATEC Behaviours.

Standard Deviation =10, MCID = 5. Range of scores deteriorated (MID <-5), improved but not significant (MCID =+5 to +9), significant change (SD = +10 and > 10). N = number of cases per range of scores (actual change scores showing number and range).

Group	N (Change) < -5	%	N (Change) >+5 to +9	MID	N (Change) +10 or >+10	1 SD / >1 SD	SIG + MID
Experimental	0	0%	3 (7,8,9)	29%	9 (10,11,13,13,15,16, 16,25,31)	56%	83%
Active Control	1 (-8)	7% -	1 (6)	7%	4 (12,15,15,23)	27%	34%
Passive Control	1 (-14)	7%	2 (7,8)	14%	2 (14,21)	14%	28%

A visual examination of participants' data indicated there was a subset of children who responded with significant change, one SD or higher or with a noticeable level of change determined by MCID scores. Tables 10-12 show how change scores were distributed in the three domains showing MCID and statistically significant change less than 0, change from 0 to SD-1, and change from one SD and above. One case improved in all three domains, and seven cases improved in two domains. Across the three domains, change above one SD was recorded in 62% of the cases in the Experimental group with five cases showing change in two domains, 47% of cases in the Active Control group with three cases showing change in two domains and in 21% of cases in the Passive Control group. It was noted that only one score fell into the negative MCID range and no scores in the range of a significant increase in severity for the experimental group while the control group had 4 negative MCID scores in Social Abilities and 2 negative SD scores in the domain Behaviours..

Several patterns were noted. Negative scores were observed more often in the active control (3 cases) and passive control (4 cases) than in the experimental control group (1 case). Children showing higher scores at baseline for each domain were the most likely to improve. In the experimental group, seven cases showed noticeable change in two domains and one improved in only one. In the active control group, two cases improved in all three domains, four improved in two domains, and three in one domain. In the passive control group, three cases improved in two domains and seven cases improved in one domain. These figures show that children may not improve in all domains. This may be reflective of the child's sensory sensitivities and the way they are experienced differently by each child, as current research illustrates the complexity of determining each individual's sensory patterns. Further research is warranted to determine the characteristics of the subset of individuals who might benefit the most from the experimental programme

4.67 Parents' Comments About the Listening Programmes

Interventions for home use are likely to be most effective when they are simple to use and pleasant to experience. Although not required as part of the study, some parents provided comments in emails or wrote notes in their listening diaries regarding their child's experience, providing a qualitative element to the study. Their words add richness to the reported results, including an understanding of the challenges of using the intervention, and at times noting small changes they were seeing in their child, that were significant to them and their families.

The cases are organized by group and categorized as Responders (change equal to or greater than one half the SD for the domain), or Non-Responders (change less than one half the SD). The last category shows comments from two parents whose children were in the Active Control group for the 20 week protocol and neither child showed any positive change. After the 40 week follow-up, their child was sent the experimental programme and both parents were thrilled to report changes they had now observed in their child.

These parents did not complete any assessments as they were not required, but were motivated to report meaningful changes. The comments are presented in Table 13.

Table 13

Parent's Comments

Case No.	**Responders - Experimental Group.**
	Responders are defined as having change scores for the domain from baseline to the end of 20 weeks of at least ½ the Standard Deviation (SD) for the domain, called Minimal Clinically Important Difference (MCID) or one Standard Deviation (SD) or greater, a statistically significant score for the domain, 95% Confidence Interval. Amount of improvement is described for each case after the parent's comment.
11	Mother reported her child "just loves the music and enjoys when it's time to listen." *Case 11 showed significant improvement for Communication and Social Abilities,* and MCID for Behaviours.
24	Mother reported they couldn't believe their child was managing to sit for 30 minutes doing his listening, that he was even asking for his listening time, so he was really enjoying it. The first week they had tried two 15 minute listening sessions, but he kept asking for more time. With a morning session, he was also becoming agitated prior to going to school. They changed to an evening schedule and let him listen to two 15 minute segments together, for a total of 30 minutes. Mother wrote again they were amazed that he could sit that long! She wrote the following progress notes, stating that her son's eye contact improved almost immediately. In week 3, he started to tell his mother when he was hearing a violin or other instrument. Mother again reported he had excellent eye contact and didn't require a fidget cushion or fidget toy during the full 30 minute sessions. In week 4, she reported that her son was conversing a lot easier, and holding a conversation for slightly longer. At the end of the 20 weeks, mother reported that her son had really enjoyed his listening time and they had seen huge changes in his behaviour, concentration, and also levels of conversations they were now having with him. The mother added that after the protocol ended at 20 weeks, they had introduced listening to similar music while he was having his iPad time and this had helped a great deal. It kept him more calm and focused and it seemed easier for him to come away from his iPad. Before, they would time him down, and he would still have a huge meltdown. But now if he was listening to the music while they timed him down, it worked really well. He continued to listen to his classical music and seemed to ask for it now if they were in a busy environment. He also does a lot of listening to music and stories at school through headphones. *Case 24 showed significant improvement for Behaviours and MCID for Communication and Social Abilities.*

44	Mother reported her daughter went from hyperactive to calm in seconds on her first listening experience and had lots of smiles. At week 6, she reported her daughter was on a school holiday and her talking had noticeably improved. At week 10, mother reported they were on holiday and her child was spontaneously using the toilet to poo that week. At week 11, the mother noted her daughter asked to do her evening listening. Week 13 she returned to school. At week 14, her mother noted that her daughter took herself off to bed at 8 pm on Monday, also that the school had commented on her talking. At week 15, mother reported her daughter was now actively asking for her music, even at the weekend. The next 2 weeks, mother notes her daughter has been agitated during her second listening session. *Case 44 showed significant improvement for Behaviours.*
46	Mother noted week 3 and 4 were very good weeks, as her child played with others outside and the following week, jumped in at swimming. At week 7, she noted it was a difficult week as her child was in hospital. NOTE: No further notes were provided, but Mother completed all the assessments. *Case 46 showed significant improvement for Social Abilities and Behaviours.*
49	Mother reported that her son listened well his first week. At week 3, he was unsettled and asked for listening at random times during the day. At weeks 4 and 5, they tried a listening time change at bedtime and evening, as he was not falling asleep easily. At week 6, her son requested his listening and enjoyed it during the day. Mother wrote she had made a visual schedule so her son knows when to expect to do his listening. At weeks 12 and 13, he was angry all the time, was screaming, and had a very difficult time. Mother decided to have him take a listening break to see if this helped. She reported her son had a much better week and a great birthday party! At week 18, mother reported her son was unsettled, but looked forward to his listening and it helped to calm him down. At week 19, the school term began. Mother reported her son reminded her of his listening times. . *Case 49 showed significant improvement for Behaviours and MCID for Communication.*
	Non Responders - Experimental Group
8	Mother reported her child kept asking to listen, so she felt it must be helping in some way. When contacted at 20 weeks to complete the last ATEC, she reported she had been unable to complete all the assessments. She had completed an ATEC at 18 weeks, which was used as the final 20 week data. She also stated she was unable to provide appropriate support for her child's regular listening, and chose to withdraw from the study at that point. She stated in an email, "we have had the year from hell." *Case 8 showed improvement was MCID for Behaviours only.*
38	Mother reported he was keen to listen in the beginning. At week 14 the family went away for a holiday and the child only listened to 3 modules during this time. On returning, he refused to listen at all. *Case 38 did not show improvement in any domain.*

	Responders - Active Control Group
3	Mother notes they were able to get him to listen mostly when he was tired and then he nearly always fell asleep before the end. The child eventually stopped listening, at about listening session number 52 (week 3) and they couldn't get him to sit for it after the initial interest. NOTE: Mother completed assessments and scores for the ATEC, which had dropped 26 points at 20 weeks. *Case 3 showed significant improvement for Behaviours.*
27	Mother began writing notes at week 14. At the end of school term there were lots of non-routine days at school, and her son had lots of outbursts and stims that week. At week 16 her son was very ill with tonsillitis and as there was a lot of driving time that week, they used it for listening sessions, as they would struggle for time the following week. Weeks 19 and 20 mother noted they did a number of catch up listening sessions. *Case 27 showed significant improvement for Communication, Social Abilities, and Behaviours*.
	Non Responders - Active Control Group
12	Mother reported in an email after several weeks that the child was covering his ears a lot, making lots of noises and was very "stimmy and hyper." She had arranged with his school for someone to supervise his listening sessions. I suggested he take a 1 to 2 week break, then try shorter listening periods to see if he would be more comfortable. After the break he went back on his 30 minute daily listening schedule with no problems. He stopped listening in the summer, at about 12 weeks of listening and left the listening equipment at his school. When he returned to school, they were unable to find the listening equipment so he didn't finish the complete protocol, but mother did agree to complete all the assessments. She wrote they did not notice any improvements during the study, consistent with his scores on the ATEC. *Case 12 did not show improvement for any domain, and showed a negative MCID in Social Abilities.*
20	Mother wrote he loves the music and sits very quietly to listen to it. Most of the time he is happy to just sit or lie down, sometimes playing calmly with his cars. He sometimes traces his finger along the wires of the headphone and mother thinks he likes the feeling. Sometimes he does actions to the music, for example pretending to play the instruments! Mother reports that generally her son is quite hyperactive so the fact he is sitting for 15 minutes is amazing and then staying calm afterwards! Mother noted her son is a lot calmer after his morning session and it has made getting ready for school a much nicer experience for everyone. Mother reported a dip in her son's behaviour when they completed the study, but it was also Christmas so she felt the dip might have been due to a bit of both events. *Case 20 did not show improvement for any domain.*

34 Mother wrote her child was very excited about the music in the first week. Although he had a disruptive week, he coped well and even got a "Star of the Week" award for trying new activities. At week 3, he didn't want to listen but continued when new toys were introduced and was happy. At week 4 he refused to listen on some days, but they were able to make up the listening time on weekends. No further notes were provided.
Case 34 did not show improvement for any domain.

37 Mother reported her child struggled with headphones the first week. At times throughout the protocol he was reluctant to listen, but he kept listening mostly on schedule.
Case 37 did not show improvement for any domain.

Additional Comments

After completing the 20 week study protocol, parents were offered the Experimental Programme for their child. These parent's comments are both about children who had been in the Active Control group and both had been Non Responders in all domains with Child No. 12 having one negative MCID in Social Abilities with the Active Control listening programme.

12 Mother had previously reported nothing had changed with the assigned programme, the active control programme. After starting the experimental programme, the mother wrote her son was listening well, that it had become part of his routine, and he would listen independently. A few weeks later, she wrote that her son had suddenly gone through a period of stammering. At approximately week 6, the ABA therapist at her son's school reported his ability to listen was getting better. At week 8 the mother very excitedly wrote that her son had started to play football with his brothers unprompted! She was amazed at his new social behaviour, which had not been seen previously. When they had completed the 20 week listening protocol, mother wrote her son's reading had improved and his social skills were better. He was now talking to his brothers and had started to become interested in football. She was delighted with the outcome.
Case 12 scores decreased MCID for Social Abilities with the active control programme.

20 Mother had previously reported that her son had a very good response to the assigned listening programme, the active control. She now reported additional changes. He previously would only write numbers or letters, for example if you asked him to draw a house he would just write the word "house." He drew in a structured way at school, but never at home. After experiencing the experimental programme, she very excitedly reported her son was drawing with chalk in the garden, had done so without prompting, and was drawing abstractly. He would say, "oh, that looks like a dinosaur" and he'd then add eyes, nose, and a smile. He was really happy and excited with his drawing. His grandmother asked him to draw a house and an ice cream and he managed to do both without getting anxious. Mother reported in the past she felt part of his struggle with drawing is that he couldn't do it exactly the way he felt it should be. She was very excited to see him draw and just go with the flow.

Case 20 did not show change in any domain using the active control programme.

4.7 Summary of Results

The primary hypothesis was supported for the domains of Social Abilities and Behaviours, which showed a statistically significant difference over the 20 week protocol for the experimental group as compared to the passive control group. Both showed a large effect size with the greatest improvement seen in the domain Behaviours. While showing a downward trend, the domain of Communication did not show a significant difference over the 20 week protocol for the experimental group as compared to the passive control group.

For Social Abilities there was not a significant difference between the three groups over time, however main effects revealed a significant effect of the experimental programme over time from baseline to 40 weeks. Further analysis between the experimental and passive control groups revealed a significant difference between the two groups over time with a large effect size. There was also a significant different in time from baselien to 20 weeks and simple main effects srevealed that the experimental group showed significant change over time but not the passive control group.

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For the domain Behaviour, there was a statistically significant change over time between the three groups. Further analysis between the experimental and passive control groups showed there was a significant difference between the two groups over time and a significant difference over time for the experimental, but not for the passive control group.

There was a downward trend for the experimental group but not a significant difference in severity of symptoms over time or between groups, as measured by the AQ Child, with no change in the passive control group. As predicted, in all three domains the active control group with no filtering had mean scores higher than the passive control but less than the experimental group. Analysis also showed that there was not a significant difference between the active control and passive control groups in any of the three domains. This partial double-blind condition was created to determine if any improvements might be attributed to the music alone. Results suggest that the filtered music listening programme did play a role in improvements seen.

The APSI, a measure of parental stress over the 20 week protocol, showed a significant reduction in stress level over time for the experimental group but not for the control group. There was a significant interaction between time and group with a large effect size. Lower parental stress levels were also seen with the active control programme.

Comments from parents whose children were in the experimental group reported improved eye contact, better focus, improvement in behaviour, in levels of conversations, and their child playing with others.

Secondary analyses of the primary measure, the ATEC, did not find a correlation between baseline scores, age, parental stress, or severity of symptoms at the 20 week outcomes in any domain, except for a correlation between parental stress levels and improvement in Behaviours. A visual examination of participants' data indicated both listening groups showed change in a subset of children diagnosed with ASC. Mean scores of the three assessments showed that in all measures for those who responded with scores greater than one SD, the mean was greater at baseline than for those who did not respond to either listening intervention. Children who responded to the experimental programme did not necessarily respond in all three domains. Further research is warranted to determine the characteristics of the subset of individuals who might benefit the most from the intervention.

5.0 Discussion

The primary goal of the randomized controlled trial was to determine the level of change by measuring three domains reported to improve in case studies and preliminary trials using the filtered music listening programme TLP Spectrum by Advanced Brain Technologies. Earlier studies suggested the programme might be beneficial for ASC children (Gee 200 , Nwora & Gee, 2011, Gee 2013, Francis 2011, Vargas & Lucker, 2016), as all showed positive trends for improved communication, social abilities, and a reduction in abnormal behaviours associated with auditory sensitivities. The present study was the first known to explore benefits in an RCT.

5.1 Main Findings

The primary hypothesis stated the experimental group would show significantly greater improvement in Communication, Social Abilities, and Behaviours as compared to the active control or passive control group with no intervention. Domains were analysed separately to provide more information about specific areas of effectiveness of the intervention and who might benefit. At completion of the 20 week protocol the amount of change in the first domain assessed, Communication, did not reach a significant level of difference over time between the experimental, active control, and passive control groups with a significance level (95%) of $p = .112$. There was a downward trend as seen with a mean decrease of 19.68 compared to a mean decrease of 2.64 in the passive control group. Reviewers of the ATEC assessment reported that the Communication domain was less effective for children with more developed communication skills (Magiati, 2011). The age range in the study, ages 4 to 8 years, may have meant that most children already had good communication skills, and communication would have been a focus in primary school for this age. In spite of the lack of significance for the domain, several parents (Case No. 24, 44, 12) did note improvements in communication abilities as reported in

Table 15. In the domain of Social Abilities, there was a significant two-way interaction between time and group with significance given as p = .008, with a large effect size for partial Eta squared (η^2) = .225, when comparing the experimental and passive control groups. In the domain of Behaviours, there was also a significant two-way interaction between time and group with significance given as p = .015 and with a large effect size for partial η^2 = .192.

The difference in effectiveness over time was predicted in the second question, that the active control group would show improvement greater than the passive control group but less than the experimental group and this was true for all three domains as shown by mean and SD for each domain, (Table 7). An additional analysis was run to examine the difference between the active and passive control groups, but significance of the two groups over time was not found in any of the domains. Results suggest that the filtering and modifications in the experimental programme did play a role in creating change, as the same level of change did not occur with the unfiltered music programme. The third question asked if any gains would maintain without listening and the experimental group maintained gains with only slight changes in the three domains at the follow up period at 40 weeks, showing lasting change had occurred as scores maintained without use of the intervention for 20 weeks after the listening protocol had ended. However, as reported earlier, the difference between groups was not significant at 40 weeks.

It is possible that neither listening programme was responsible for the reported changes. Following established routines are important for ASC children and establishing a daily routine of 30 minutes total of focused listening and quiet activity time, may have been beneficial. The passive control group did not follow any protocol so the daily listening routine may have contributed to the difference between groups. Parents who become involved in studies may have greater hope and expectations of positive outcomes, which may affect how they interpret effectiveness. Assessments may help a parent understand their child's difficulties better, and motivate them to find additional ways to support their child. It is also possible that both listening programmes simply provided a pleasant and relaxing distraction for a short time each day from household noise such as dish washers, television, or siblings using computer gaming devices, helping them to cope.

A larger sample size may have yielded different results. The complexity of sensory sensitivities across the autistic spectrum means it is difficult to assess and predict who might best respond. When best responders can be identified, and a larger sample of those who are assessed as possible responders are recruited, results using the experimental programme may change. As the first RCT, this small study answered several basic research questions about the effectiveness of the experimental programme. Was it effective in the home setting under the supervision of a parent, without the help of a therapist? Was the filtered music programme more effective than the unfiltered music programme? Would any reported changes maintain after a 20 week period without listening?

Results of the RCT support previous studies showing the intervention consistently exhibited positive trends for effectiveness in areas associated with auditory sensitivities. In addition, studies using brain imaging were cited in the literature review that show the auditory pathway does change with auditory input, suggesting the possibility of reducing auditory hypersensitivities with appropriate auditory input and listening protocols.

The experimental programme was not created to be used solely as a one time only exposure, and it may be used differently under real world conditions. Presently it is only available from a trained therapist who generally uses it in combination with the treatment they have determined to be best practice from their field of specialty. They not only oversee the implementation of the programme, but may recommend listening beyond the 20 week protocol used for the study. The programme may become a helpful tool for stressful times in a child's life. Plasticity means change and can be positive or negative. Change can mean an improvement, but in the case of consistent exposure to noise over time for example, a worsening of sensitivities may occur. In this case a child may again benefit from another listening protocol, and the therapist may suggest the best range of modules and the length of the exposure. The focus of this RCT was to first explore the effectiveness of the experimental programme as it is currently used in the home.

The three groups were nearly equal in size, with 16 and 15 in the two listening groups and 14 in the control group. Each group proved to be comparable in age but the sample was too small to count gender as a factor with just six females recruited for the study, as reported in descriptive statistics. Scores for severity of symptoms ranged from mild to severe in each group and any differences between groups were comparable. Developmental change in the young age group of 4 to 8 years would be expected over a period of 10 months, so even without intervention, most children would be expected to show some change with age.

It was not possible to ensure everyone followed the protocols, as listening was done in the home under the supervision of a parent. Some participants did report partial completion of the 20 week protocol. In the experimental group, one child completed 12 weeks, then told his mother he was finished. A second child's mother said listening was inconsistent as they'd had such a difficult year and the last ATEC completed was at 18 weeks before they withdrew from the study.

In the active control group, one child completed only 12 weeks, another stopped at 6 weeks, complaining of hating the experience and afterwards would not wear headphones at all. One child refused at 6 days saying she hated the music and it irritated her, another had listened about 10 weeks but the mother reported her child had either disliked the music or was having sensory issues and they withdrew from the study.

Targeted outcomes may be difficult to determine in any spectrum condition. This is especially true for sensory sensitivities seen in ASC, which can be expressed with complex and varied reactions, and associated behaviours varying with each individual child. Research is beginning to provide a greater understanding of multisensory sensitivities and the associated behaviours such as a study undertaken by Watson et al., (2011) to classify language, social, and communication difficulties in ASC according to sensory response patterns. The investigators focused on three response patterns: hypo- and hyper-responses and sensory seeking, and found a link between hypo-responsive patterns and more severe social-communication symptoms. This type of research should help to identify characteristics that may identify a best responder to the experimental programme in the future. However, at the start of the trial there were no identified exclusion criteria that might suggest a pattern of response for the study so any child who had a diagnosis of ASC from a qualified health professional was allowed to enrol, if they were not enrolled in another intervention and did not also have a genetic or major medical diagnosis in addition to their ASC diagnosis.

A wide variety of assessments had been used to evaluate auditory stimulation programmes, as reported by Sinha et al. (2011), in the Cochrane Review for Auditory Integration Training and other sound therapies for Autism Spectrum Disorder. Auditory processing and abnormal auditory sensitivities are not seen exclusively in ASC and may be treated by speech therapists, OTs, psychologists, and educators, who each have their own preferred assessments. The decision to utilize a specific assessment is important, as it may reveal or conceal the actual effects of an intervention, depending on the general topics and specific questions asked.

5.11 Vineland Adaptive Behaviour Scales

At the time the study was designed, the Vineland, ATEC, and the AQ Child, were believed to address most of the trends and items noted by case studies and preliminary trials of the experimental programme as likely to improve. The APSI was seen as an important additional measure, as a self-selected parent was responsible for the programme's usage in the home, which might also contribute to stress if the intervention was seen as difficult to implement and supervise. All assessments but the Vineland were easy to complete in 10 to 30 minutes time, and all were able to show degrees of change using Likert scales.

The Vineland was selected as it had questions in the selected domains and was a better assessment for communications skills than the ATEC. When evaluated by Magiati et al. (2011), the ATEC was found to be promising in many ways, but the authors suggested for the communication category, it may be more beneficial for children with "less well developed communication skills." (p. 16). The Vineland has an edition that was designed to be completed by a parent or teacher. In practice, this edition did not provide accurate enough directions for easy use and all parents did not answer the same number of questions. Even when the booklets were returned to a parent with extra, very specific directions written next to the questions, not all parents complied. After a careful review of the VABS booklets, it was decided that using the ATEC as the primary assessment would be a better choice.

5.12 Autism Treatment Evaluation Checklist (ATEC)

Recreating the remaining three assessments online and providing links in emails to each parent, proved to be a better way to collect data for the majority of participants. Just two parents asked for paper assessments rather than digital. For any future research, a thorough review of assessments currently available should be undertaken. One of the parents in the feasibility study said that she was seeing changes in her son that were not reflected in the assessments. The ATEC fulfilled an important requirement, but did not cover as many details for abilities that might be expected to change, particularly in the domain Communication. There may be a more valid and precise way to assess all effects of a listening programme. For this trial, it was determined that assessing the three ATEC domains separately would provide additional information about who is most likely to respond to the intervention and how they might respond.

Scores for the small sample failed to meet the required level of significance between groups over time for the ATEC domain Communication, but did show a significant interaction between time and group for the domains of Social Abilities (p = .008, with a large effect size, partial Eta squared = .225),and Behaviours (p = .0005), with a large effect size, partial Eta squared = .3690.

5.13 Research Questions

Two additional research questions concerning the experimental programme were explored. The first question asked if the same results might occur with unfiltered music listening. The active control group, using a repeated measures ANOVA, showed a consistent improvement in scores in each domain grater than the passive control group, but less than the experimental group, (Table 8). Evidence from other studies (Bettison 1996, Porges et al., 2014, Francis 2011) has indicated that music listening using a structured programme was beneficial, and results of the present study support the regular structured use of music listening as well. While it was not shown to be as effective as the experimental programme, some children did respond with significant or MCID change in scores. Older ASC individuals report using music to focus and as a distraction in noisy environments ((Elwin et al., 2013) and parents may find it beneficial to use regular music listening with younger ASC children who exhibit auditory sensitivities. The second question concerning the experimental programme was asked to determine if any reported effects would be maintained over time. Results are shown in Table 7 and do show that changes were maintained over time, without listening for 20 weeks, with only a slight change in mean scores.

5.14 Autism Quotient (AQ Child)

The Autism Quotient measures severity of symptoms and was selected for two reasons. The first was to ensure that the range of severe to high functioning cases would be balanced in each group. The second was to measure change at 20 weeks as the theoretical basis of the intervention is to reduce symptom severity, particularly those symptoms associated with auditory sensitivities. Item number five, *S/he notices small sounds when others do not*, is the only question of 50 directly citing sound sensitivities, while a number of other questions have been associated with auditory difficulties as described in the literature review. Many of the AQ Child items relate to social abilities and communication, as core symptoms of ASC. Auyeung et al. (2008) did suggest that the AQ child might be a useful measure for following the trajectory of change for an ASC child over a lifetime. Data produced by the repeated measures ANOVA showed changes in symptom severity at 20 weeks for the AQ Child, showing improvement for the experimental group, but not for the active control group and only small change for the passive control group. While not showing significant change compared to the passive control group, the data for the experimental programme did show a downward trend in decreasing severity of symptoms. This was predicted in the sensory theory of autism, that many of the abilities and behaviours seen as symptoms of ASC are actually coping mechanisms for sensory overload. If the sensitivities can be reduced, many behaviours considered 'autistic" will be reduced and more normal age appropriate development can occur. While not significant after adjusting for baseline scores (p = .081), a downward trend of lower symptom severity in 20 weeks for the experimental group was seen as encouraging.

5.15 Autism Parental Stress Index (APSI)

The APSI is not a rating of efficacy of the programme, but a subjective report by parents of their perceived stress before and after the intervention. It is considered an important aspect of the effectiveness of any intervention, particularly one used in the home under the supervision of a parent. The practical aspect of an intervention is that implementation should not be too difficult, the intervention should fit into family routines, and should ultimately reduce the level of stress for the parent as well as the child. Karst and Van Hecke (2012), when writing about the parent and family impart of ASC, remind investigators that it can never be assumed that a successful outcome will mean that stress levels are lowered. They argue that assessing stress should always be done in conjunction with assessing any intervention. In this case, parents using either listening programme reported in nearly equal measure that stress levels were reduced. While not significant, there was a consistent improvement over the passive control for all domains for children using the active control listening programme. As mentioned earlier, following established routines are important for ASC children so it may have been that establishing a daily routine of 30 minutes total of focused listening and quiet activity time, was likely beneficial. The passive control group did not follow any protocol so the daily listening routine may have contributed to the difference between groups. It is possible that both listening programmes simply provided a pleasant and relaxing distraction for a short time each day from household noise such as dish washers, television, or siblings using computer gaming devices, helping the child to cope and giving the parent a break as well.

Parents in the experimental and active control listening group reported a significant reduction in stress levels after 20 weeks of their child using the programme, suggesting the programmes were seen as relatively easy to manage as well as effective. No change in stress levels was reported by the passive control group. The APSI is short, just 13 items, but targeted specifically for the types and severity of stresses common to parents and caregivers of ASC children (Silva & Schalock, 2012). This is reflected in the range of five choices fore each item, from *Not stressful,* to the last two options of *Very stressful on a daily basis,* and *So stressful sometimes we feel we can't cope*.

Silva and Schalock (2012) also suggest the impact of an ASC child's difficulties is often compounded in the family. For example if a child does not sleep well, the parents will also be sleep-deprived, making meltdowns and aggressive behaviour more likely for a tired child, and more stressful to manage for an exhausted parent. In addition to individual parental stress, the marital bond, siblings, resources, and quality of life can be affected. As expressed in the parent's comments, even small changes that occurred may have improved family life and may have given a parent hope for their child's future. This makes the significant improvement in stress levels an important benefit of the intervention. It also suggests that a regular daily listening to music session that the child enjoys may be an effective way to lower stress in the household.

5.2 Comparison to other Behavioural Interventions for ASC

Two treatment outcomes are reviewed here to provide perspective and comparison for the present study, as both are described as behavioural interventions for use with young children. Applied Behaviour Analysis, ABA, is known as an early and intensive behavioural intervention for ASC. ABA treatments are considered to have strong supporting research with over 2000 replicated studies with a single system design, plus RCT's, and meta analyses, (Keenan et al., 2015). ABA interventions are not as widely used in the UK or the EU as other trialled treatments, however in the US, insurance coverage of the treatments was noted to exist in 43 (of 50) states (Roane, Fisher, & Carr, 2016). Twenty-four of these states also have laws that regulate ABA providers. They note that ABA is not a single treatment, but a field of study having certain principles and procedures.

The first of these types of treatments was created by Lovaas, who developed what was commonly called an early and intensive behavioural intervention (EIBI or IBI). In a review of interventions for autism that are evidence-based, Mesibov and Shea (2011) refer to the Lovaas programme as one of "the best-known and most popular autism intervention programmes in the United States." The Lovaas treatment is now known as the first intensive ABA treatment (Roane, Fisher, & Carr 2016). Today there are a number of other approaches developed as adjuncts to this early model.

An IBI study by Eldevik et al. (2010) used participant data from 16 previous group design IBI studies measuring individual IQ and adaptive behaviour for a final analysis of 357 children aged 2 to 7 years, 248 in the IBI group, 70 in the control group and 39 in the comparison group. Training for the intervention was 20 to 30 hours per week for 2 or more years. Reliable change (95% CI) for adaptive behaviour was seen in 20.6% for IBI as compared to 5.7% for a comparison intervention and 5.1% in a control group.

A second approach under the ABA model was developed specifically for very young children and is called the Early Start Denver Model (ESDM). ESDM is delivered in the home by trained therapists and parents, similar to the listening programme in the present study. The ESDM was evaluated in an RCT with ASC children aged 18 to 30 months (Dawson et al., 2009). The ESDM group of 24 children had 31.5 hours per week of treatment by clinicians and parents, and the Assess and Monitor (A/M) group of 23 children, had 18.4 hours per week of individual therapy and group interventions. The

A/M group were given referrals to ASC providers in the Seattle region. Results were measured at one and two years.

The adaptive behaviour domain of The Vineland Adaptive Behaviour Scale (VABS; Sparrow et al., 1984) evaluates communication, daily living skills, and socialization, similar to the ATEC used in the present study (Magiati et al., 2011). At one year, the groups were similar for adaptive behaviour, both showing a small decline, but at two years the ESDM group outcomes showed significant gains in language and adaptive behaviour. ADOS severity scores, similar to the AQ of the present study, showed the two groups did not differ. The authors (Dawson, et al., 2009) report they believed parental involvement was likely an important ingredient of its success.

The ESDM and IBI were both conducted by trained therapists with parental support for a combined training time of approximately 30 hours per week per child, for 2 years. In the present study, children had only parental support at home, and listened for 30 minutes a day, 5 days per week, for 5 months. After one year, there was no difference in adaptive behaviour for the ESDM group of 24 children (Dawson et al., 2009), but at two years, outcomes showed significant gains in language and adaptive behaviour. In the IBI group of 248 children, change in adaptive behaviour was seen in 20.6% of children (Eldevik et al., 2010). Results for the experimental programme compare favourably to these two other programmes in a shorter time frame, but also did not show improvement for all participants, as expected.

5.3 Parent's Comments

Parent's comments provide a qualitative element to the trial results. Reports were not required, but some parents wrote emails to the investigator, and others wrote notes in their listening diaries, which they returned to the investigator. For some children there was a struggle with headphone usage. Over the 20 week protocol there was at times illness in the family and changes in school schedules that interrupted the listening schedules. These often caused problem behaviours, but parents were creative with fitting daily listening times into a child' schedule, and with responding to a child's reactions to listening. Difficulties encountered and adjustments made to scheduling, were explained by some parents. It is interesting to note that for one child, morning listening made him agitated, but for another child, morning listening helped him to remain calm and get ready for school. This illustrates why flexibility is important in any ASC intervention. A number of the children loved their listening times, and five parents reported their child in the experimental group asked to listen.

The comments given by parents illustrate that even small changes can be extremely meaningful within the family. These are not necessarily noted by questions in an assessment, as the mother of the first child in the Feasibility study stated. The first time a child spontaneously does something without prompting is a notable change for a parent and often the whole family. A child beginning to be more social, perhaps by spontaneously joining siblings in play or other students at school is a huge step. When a child establishes eye contact with a parent, it may deepen the relationship a parent has with their child. When a child is finally toilet trained, daily life is less hectic, leaving the house with the child becomes much easier, and the cost of nappies/diapers can be dropped from the family budget.

5.4 Secondary Analyses - Additional Findings

Severity of symptoms was measured by the AQ Child and was first used to determine if the groups were equivalent. Secondly a repeated measures ANOVA was run to determine if there was any change in severity of symptoms for those using the experimental programme. While the results were not statistically significant, there was a downward trend towards significance, supporting results of the ATEC in reducing behaviours associated with auditory sensitivities. Parental Stress was also measured as recommended for any in home intervention overseen by parents for ASC. Parental stress levels were significantly reduced in the experimental and active control groups as compared to the passive control group

Analyses of the ATEC data using analysis of covariance, ANCOVAs, were run to determine if age, severity of symptoms or parents' stress levels might have affected the scores for any of the three groups. Analysis did not reveal significant differences between the mean scores when adjusted for baseline Communication scores $p = .773$. for age $p = .770$, severity of symptoms (AQ Child) $p = .842$, or parental stress (APSI) $p = .16$. This was true for all three domains with one exception. There was a positive correlation between parental stress levels and a reduction in abnormal behaviours.

There was a consistent pattern of greater change with the experimental programme as compared to the active control, or the passive control. This was apparent first in a repeated measures ANOVA of the ATEC data by domain, and showed the mean scores for the active control group were between the scores for the experimental and the passive control group for each domain as predicted. An additional analysis did not find a significant difference between the active control and passive control over time in any domain. Music is regularly used to alleviate stress and was expected to help children with auditory sensitivities to cope better than no intervention. The results indicate that filtering and other modifications in the experimental programme do play a role in affecting change. This was also seen in the two children who had received the active control programme during the study, then the experimental programme. Both parents reported seeing positive changes in their child after using the experimental programme, not seen with use of the active control.

5.41 SPSS Case Summaries

A visual examination of SPSS Case Summaries (Appendix L) for each domain revealed a number of other differences between the responders and non-responders and between the three listening groups and data are presented in Tables 10-12. A responder is described as having improved scores that are significant statistically (One SD or higher) or as having a minimal clinically important difference (MCID) or one half SD as defined by Norman et al., (2003), indicating change that may be observed but scores do not reach statistical significance. Percentage of change occurring for the experimental group ranged from 81% for Behaviours to 31% for Communication. For the active control group, rates of change ranged from 40% for Social Abilities to 26% for communication. For the passive control group, change ranged from 28% for Behaviours to 7% for Communication.

The non-responders also showed variability between groups. One difference was noted in frequency and severity of negative scores, showing deterioration in abilities or behaviours. For the experimental group, there was one case showing an MCID decrease in mean scores in the Social Abilities domain, indicating a worsening of assessed abilities. The active control group of non-responders had two significant scores in the negative range, a significant worsening in Social Abilities, and in the passive control group, three scores in the negative range in Social Abilities, and one significant negative score in Behaviours (Tables 11 – 13). Because the experimental group had fewer cases of deterioration in all three domains, it is possible that the experimental programme may have prevented deterioration, but a larger sample would be needed to explore this factor.

Results for responders in this study are similar to other therapies and interventions used by parents for ASC. A study by Goin-Kochel, Mackintosh, & Myers (2009) analysed a questionnaire from 479 parents who had tried various treatments and therapies. Parents reported improvement overall of 50-80%, which included changes noted from small to dramatic in the categories of drugs and diet, and educational or behavioural interventions. To a parent of an ASC child, small differences can be very significant, suggesting the addition of the MCID scores to the trial results could be seen as useful and more consistent with other reports.

The latter category of behavioural interventions included early intervention, OT, social skills training, and speech therapy and had been tried by over half the families in the study. Approximately 70% were rated as creating improvement, but within this subjective category, “the most common rating was ‘child improved somewhat’ followed by ‘child improved dramatically’” (Goin-Kochel, et al., 2009, p. 528). With both somewhat and dramatically in the same category, the scale suggests percentages would be higher than ratings based only on statistically significasnt data from an RCT, however the description “somewhat improved,” might be compared with the MCID description for change.

There were some differences noted in those considered responders and non-responders in the study. Mean scores in all three assessments were higher at baseline for responders. The consistent pattern in all assessments suggests that a child with more severe symptoms may be more likely to respond to the interventions, although severity did not guarantee improvement. It was noted that four cases in the experimental group who showed either MCID or significant improvement improved in all three domains, seven cases showed improvement in two domains with six of these cases improving in Social Abilities and Behaviours, and two cases showed improvement in only one domain, in Behaviours. This might be expected as the range and severity of sensory symptoms is complex and differs for each individual.

The behavioural domain in the ATEC (Appendix J), included questions associated with health issues, and showed significant improvement for the experimental group. The domain asks about continence and elimination issues, which included toileting, constipation, and bed-wetting. Questions in the area of behaviours ask about flexibility as observed in routines being less rigid, a lesser demand for sameness, and a decrease in obsessive speech. Questions also include dietary habits, whether a child is eating too much or too little, and if a child does not have a sensitivity to pain. Sensitivity to pain is a very important safety issue as a child who does not feel pain and/or is not able to communicate may not report an injury, continue playing even with a bloody knee, or not express discomfort when he is ill, leading to a delay in treatment.

Some of the change reported in Parent's Comments (Table 13) were: "improved eye contact," "levels of conversation have improved," "took herself off to bed at 8 pm.," "holding a conversation for slightly longer," huge changes in his behaviour, concentration, and also levels of conversation we are now having with him," "jumped in at swimming this week," "has started to play football with his brothers unprompted," "his reading his improved and his social skills are better," and " now drawing pictures unprompted and abstractly."

Common themes were a decrease in negative behaviours, and an increase in social abilities, starting with improved eye contact, as predicted by Porges's theory of social engagement (Porges et al., 2013). Some abnormal sensory responses may improve with age including sensitivity to sound, while others are known to persist through adulthood. The ESDM, mentioned earlier, did not show adaptive behavioural change at one year but at two years showed gains over the A/M group, and the IBI showed change in 20.6% at two years. It is possible that alleviating sensory overload for a child who shows abnormal auditory sensitivity may prove to be a quicker, more effective method to promote change in social abilities and adaptive behaviours. If sensitivities are addressed at an early age, a more normal pattern of development may occur depending on the individual child's strengths and weaknesses. It may be that addressing sensory sensitivities first, at an early age, would allow other treatments to be more effective.

The present study did not show significance for the experimental group in the domain Communication, but more targeted studies may show improved outcomes in this domain. The scores not reaching significance for communication may be related to the weakness of the ATEC for the communication capabilities of the older children in the study as stated in the review by Magiati et al. (2007). Some parents commented in diary notes that their child's communication skills had improved. Three parents reported on improved communication skills in their child including noting improved reading, improved talking which was also reported by the school, and being able to hold a conversation longer.

Results shown in the present study are consistent with results of earlier studies for the experimental programme. In addition to Jeyes (2013) cited earlier, the studies included Nwora and Gee (2009), Gee et al, (2013) and Gee et al., (2015) who reported noticeable improvements in behaviours, multisensory processing, and social abilities. Francis (2011) reported positive changes were most apparent for children with sensory processing difficulties, and that the five Rett learners (classed as ASC at that time) showed most change in sociability and mood. Vargas & Lucker (2016) reported the second largest effect size of nine studies using Hedge's g formula (1.19) was seen in an ASC study measuring auditory processing abilities, which may be defined as the brain's ability to accurately interpret what it hears. The authors noted that larger effect sizes were seen in studies using the experimental programme and assessing auditory processing and listening skills (mean effect size 0.72), than non-auditory areas (mean effect size 0.31).

5.42 Parent's comments about the listening programmes

Interventions are likely to be most effective when they are simple to use and pleasant to experience. The majority of children did not have a problem with either listening programme, but there were some exceptions. A few parents provided comments in emails or in their listening diaries regarding their child's experience and were reported in Table 13, to provide further insights into their experience with the music, listening equipment, protocols, and additional details about observed changes.

Parents were creative with fitting daily listening times into a child's schedule, as suggested in the guidelines, and with responding to a child's reactions to listening. It is interesting to note that for one child, morning listening made him agitated, but for another child, morning listening helped to calm him and get ready for school. A number of the children loved their listening times, even asking to listen.

After the 40 week study had ended including completing final assessments, the parent was notified of their child's listening group assignment and were given the opportunity for their child to experience the experimental programme if they had not done so during the study. The control group was also given the experimental programme. No assessments or reports were required, but two families voluntarily reported their child's results. Both children had previously had the active control programme, and were now listening to the experimental programme and were seeing changes in their child.

The comments given by the parents illustrate how even small changes can be extremely meaningful for the parent and within the family. They are not necessarily noted by questions in an assessment, as the mother of the first child in the Feasibility study stated. The first time a child spontaneously does something without prompting is a notable change for a parent. A child beginning to be more social, perhaps by spontaneously joining siblings in play or at school is a huge step. When a child establishes eye contact with a parent, it may deepen the relationship a parent has with their child. When a child is finally toilet trained, daily life is less hectic, leaving the house with the child becomes much easier, and the cost of nappies/diapers can be dropped from the family budget.

5.5 Negative Reactions

Two negative reactions were reported of the 45 children concerning their listening experience and both of the children were in the active control group. One negative reaction appeared to be due to the child's sensitivity to the headphones. The mother reported it took awhile for the child to get used to the equipment. Later she wrote it was with great regret, but she was withdrawing her child from the study as he was becoming more and more distressed with wearing the headphones and listening. I suggested a break in listening, but the mother chose to withdraw from the study, again citing the child's distress. Only baseline assessments were completed. This case illustrates why the programmes are available only through a trained professional. If the parent had obtained the programme through an OT for example, sensitivity to touch would have been treated before starting the listening protocol and the headphones may not have been a problem. It is also possible that it was the unfiltered music that was causing the negative reaction with the child, as this was not clarified by the mother.

The second negative reaction was an 8 year old child, again in the active control group, who as reported earlier, listened for one week to unfiitered Mozart at her mother's insistence. She often shouted out that the listening session was stupid, she hated the music, and wished the session were over. At the beginning of week two, she refused to listen at all. She again told her mother she hated the music and that it really irritated her. I agreed with her mother that it was best to withdraw from the study, as music listening should be a pleasant experience, and considering her daughter's reaction, it wasn't likely to work for her.

5.6 Strengths and Limitations of the Study

There are a number of strengths in this study. First, it is a randomized controlled trial, considered the gold standard in determining the efficacy and effectiveness of an intervention. Parents were asked to confirm the ASC diagnosis and all selection criteria, including not being concurrently involved in another intervention. Each child was assigned a case number as they were accepted into the study and allocation to one of the three groups was blind, done by a colleague in another office using a random number generator. Two listening groups allowed participants and the researcher to be blind to the listening programme assignment. As the control group had no listening, it was clear who had been assigned to this group, making this a partial double blind study design.

The trial was undertaken in a real life setting, with all the distractions and difficulties of daily life. Listening took place in the home, so travel time to a clinic or other setting and home appointments for outside therapists or other professionals were not necessary. The families in the study had many challenges causing some to drop out, but most were able to manage, and find a way to make regular listening a routine part of their child's day. The protocol extends listening for 5 months, a time period that is long enough for at least some results to be observed and for some changes to solidify. In actual practice, listening time may be longer if the therapist or educator overseeing the programme believes the child would continue to benefit.

The investigator had no physical contact with parents, which helped to avoid any possible biased reporting. All but one family were outside of Edinburgh. Information was given in a booklet of guidelines and the parent could ask questions via emails. An attempt was made to assist a parent to get started with listening if the child had difficulty wearing the headphones, but once listening was underway, there was little or no additional personal contact. All measures were self reports by parents, so there was no observer bias by investigators.

The study attracted both severe and high functioning children with a range of difficulties, within a small age range. Standardized measurements covered basic communication skills, social abilities, and difficulties in managing behaviours including those associated with health.

Limitations of the study include the following. Theoretically the programme is meant to normalize a child's reactions to sound, yet no attempt was made to preselect participants based on sensory difficulties. It was known that not all children would respond, but there was no research indicating characteristics of best responders that might be used as inclusion criteria.

The programme is an at-home intervention and overseen by a parent. Written information was given, but it was not possible to know how well these directions and guidelines were followed. Although efforts were made to track compliance with a listening diary, some parents completed and returned the diary, others did not.

Parents completed all assessments. This can be considered a strength, as parents observe their child nearly 24 hours per day and generally have reports about the few hours of daily schooling. It can also be considered a limitation, as the reports may be subjective. Some completed the weekly assessment regularly, some occasionally, and others completed only the pre and 20 week assessments. Transitions are difficult for ASC children so if there were health issues, problems at home, changes in school schedules, and so forth, behaviours might suddenly change the week the parent is completing a questionnaire.

The 20 week listening protocol required dedication on the part of the parent to oversee the programme daily. By signing the participation agreement, each parent also agreed not to use other interventions for an additional 20 weeks, but there was no attempt to determine if the parent had complied.

Blinding was only possible for all participants in the two listening groups. The experimental programme had to be reloaded onto the iPods by the company in the US, so children who did not have the experimental programme in the study or were in the control group, could then listen. Because of the long recruitment period of 10 months, at about 20 weeks the first group was finishing their listening protocol, and the remaining participants were at various stages in the protocol. It became necessary to know which programme had been assigned in order to request the return of all the listening equipment and/or the iPod, and return them to the US supplier where they could be reloaded with TLP Spectrum and returned to the researcher in Edinburgh. To ensure remaining blind to group allocation, no action was taken until all 63 participants had been assigned to a group. At that point the supplier was contacted to ask which group had been assigned to the experimental programme. Although this was not ideal for the investigator, it was necessary. Contact with parents was minimal at that stage, except to send a standard email requesting completion of the assessments at 20 weeks.

5.7 Future Research

The goal of the present study was to test the effectiveness of an edition of a filtered music listening programme for young children ages 4 to 8 years of age diagnosed with autism. The experimental programme is an edition that was created by the supplier for individuals with "especially sensitive hearing", especially for autism and brain injury, and is normally used in the home, under the supervision of a trained therapist. For this study, the programme was overseen by a parent in the home, for a minimum 20 week protocol. As an initial RCT, this study was designed to measure change in three domains that were previously reported as showing trends for improvement in a number of studies using the programme.

The experimental programme was not created as a one time only exposure, and it is often used differently under real world conditions. Presently it is only available from a trained therapist who usually recommends it in combination with the treatment they have determined to be best practice from their field of specialty. The therapist not only oversees the implementation of the programme, but depending on the child's response, often recommends listening beyond the 20 week protocol used for the study. Some children have more severe auditory sensitivities and while they may experience improvement, they may continue to benefit from continued listening. Also with consistent exposure to noise over time, a worsening of sensitivities may occur. In this case a child may again benefit from additional listening sessions, and the therapist may suggest the best range of modules and the length of the exposure to the programme, based on their experience.

A larger sample may have yielded different results. Testing change over a longer period should be included in future trials. Relieving some of the burden of sensory distractions should allow a child to continue to improve. A child in the feasibility study began to ask questions that his mother suggested allowed him to catch up on things he should have already learned for his age, and his mother reported he went from a half day with an aide in school to a full 5 day schedule over a period of several years.

Future research should first seek to determine how to define a best responder, as the theoretical basis of the programme is to reduce auditory sensitivities and associated behaviours. This predicts that those with auditory sensitivities should become best responders. The present study was advertised for children who might have sensory sensitivities but allowed anyone with a valid diagnosis of ASC to participate if they met the inclusion criteria. In the future defining characteristics that include the four different ways an individual may react to sound might be used as inclusion/exclusion criteria for a study, and outcomes might more accurately show a treatment effect. It is possible some of the children in the study did not have sensitivities to sound and therefore no treatment effect should have been expected. One of the difficulties lies in identifying the type of response and assessing associated behaviours that are reported to improve by parents and individuals who have used the programme. Parents often report changes that are meaningful to them that are not listed on an assessment. The Short Sensory Profile (SSP; McIntosh, Miller, & Shyu, 1999) has a small section called Auditory Filtering, which lists nine associated behaviours.

A recently created assessment, the Auditory Behaviour Questionnaire (ABQ) expands the descriptions of behavioural responses to sound seen in ASC children. Authors Egelhoff and Lane (2013) report that current auditory research lacks a formal assessment that measures only auditory behaviours and the categories of response that have been identified. They believe the ABQ will fill a gap in helping parents and clinicians identify these behaviours that are observed in response to auditory stimuli. The questionnaire lists four categories describing the type of reaction, and with a larger number of associated behaviours for each. The categories in the ABQ are: Difficulty in background noise, listing 11 behaviours; Aversive reactions, 11 behaviours; Unresponsiveness, 8 behaviours, and Stereotypic/repetitive behaviours, 10 behaviours. Egelhoff and Lane are also hopeful the questionnaire will help to assess patterns of behaviour, and can be used to improve intervention. The questionnaire may shed light on best responders to the experimental programme, by examining a larger number of behavioural responses and identifying the type of reaction related to the response.

In the past decade more research has been undertaken to identify sensory patterns in ASC children. The four performance factors listed in the ABQ above are part of this research. The performance categories may be used to describe any of the seven sensory categories for stimuli: sound, touch, vision, hearing, smell, taste, vestibular, or proprioceptive. In addition, sensory and performance categories have been investigated and associated with specific abnormal behaviours. Further development of the ABQ questionnaire will be especially useful for assessing filtered music listening programmes.

Reactions described by ASC individuals earlier in this thesis described their experiences as multisensory. A study by Lane et al. (2010) found combinations of sensory responses and their severity predicted difficulties in competencies and abnormal behaviours. They examined data for 54 ASC children who were registered with an early intervention research programme in South Australia. Cluster analysis was used to analyse data from the Short Sensory Profile (SSP; Dunn, 1999) and the Vineland Adaptive Behaviour Scales (VABS; Sparrow et al., 1984) and then compared results to 1,200 neurotypical children.

Three distinct sensory processing subtypes emerged from cluster analysis for the ASC group and each is associated with specific behaviours. The first subtype, found with the majority of participants, was associated with attention difficulties and combined a definite difference in auditory filtering (92.6%) with hypo-responsive/seeks sensation (85.2%) as compared to typical (Lane et al., 2010). The second subtype was associated with movement difficulties such as poor posture and grasp and low endurance. Dysfunction was severe in all sensory domains presenting as both hypo and hyper-responsiveness. The third subtype was associated with impaired communication and combined all categories of sensory difficulties with extreme sensitivities in taste/smell, but not with movement. The sensory domains that most strongly characterized the subtypes were sensitivities in auditory filtering, taste/smell, and movement. The authors suggest these domains be studied further to understand sensory response patterns along with interventions that may remediate communication and behavioural difficulties. The study added to the complex description and understanding of sensory reactions and associated behaviours.

A second study by Lane, Molloy, and Bishop (2014) again looked at subtypes, this time examining sensory subtypes at the time a child was diagnosed to see if the data were consistent with their previous studies (Lane et al., 2010) or if sensory subtypes might have changed over time. The investigators looked at age, gender, symptom severity, and IQ in relation to sensory subtype. Participants were aged 2 to 10 years, diagnosed with ASC between 2008 and 2010 at a major US autism centre and each had completed a large battery of evaluations at the centre (n=228). One of these evaluations was The Short Sensory Profile (SSP; McIntosh, et al., 1999a), which had been used to examine sensory differences. Cluster analysis was used to determine sensory differences in the data and four categories were revealed. A category named sensory adaptive described 37.5% of the children as having "mildly elevated scores in auditory filtering and under-responsive seeks sensation" (p. 7). This category showed a lower incidence of children with sensory differences than previously reported, with one previous study reporting an incidence at high as 92% (Tomcheck & Dunn, 2007). The other categories were the same as the 2010 Lane study described above. Sensory differences were not related to age, IQ, or severity.

The authors (Lane et al., 2010) believe that establishing sensory subtypes will lead to improved evaluations and more appropriate intervention. There is still some confusion with naming categories differently by different investigators. As more research is undertaken with subtypes, consistent descriptive categories should be used. The term auditory filtering as a category of response to auditory stimulation, continues to be associated in varying degrees of severity with a number of sensory symptoms and combinations. In these two studies, three factors combine to indicate the behavioural category: the sensory category or combined sensory categories, the performance category, and the severity, and all of these factors in specific groupings are linked to an associated behaviour. As more is known, best treatment for subsets of children with auditory sensory sensitivities will emerge.

For some people, experiencing one sense automatically triggers a different sense so that colours may accompany sounds, letters may always have a certain colour, or a word may always have a specific taste. This is known as synaesthesia. Baron-Cohen et al., (2013) looked at the presence of synaesthesia in autism, noting the description of an ASC individual's sensory experience was similar to those with synaesthesia and that both had shown to have an increase in brain connectivity. Earlier in this paper, an ASC individual named Gerland gave an example of her combined sensory experience (2003, p 54, cited in Davidson, 2010). She explained that when she touched a metal button or jewellery, she would hear an odd sound, and feel her stomach turn over. Data from the Baron-Cohen questionnaire indicated that synaesthesia is nearly three times greater in those with autism, suggesting both may share similar underlying mechanisms. As research emerges in this area, findings may provide information about the multisensory nature of an ASC individual's experiences as well.

5.8 Generalisation of Findings to Other Listening Programmes

The results reported in this study cannot be taken as support for other auditory listening programmes in this field. As noted previously, the many programmes are quite different, and reflect the approaches of their creators. They may use different music, have different protocols, and support different theories that underlie the filtering and modifications employed in their creation. The present paper shows that more recent science does not always support the theories and ideas leading to the creation of the first programmes. For the dozen or more listening programmes claiming to treat ASC, research data needs to be provided to show any change created by each programme that may be greater than a control group with no intervention and a similar unmodified music programme to determine if their music and filtering protocols may be associated with any reported change.

5.9 Clinical Importance

At present, there are few clinical recommendations for helping an individual with abnormal auditory sensitivities other than general suggestions about finding a quiet spot for an agitated child, providing them with headphones in a noisy setting, and/or simply avoiding noisy events.

Therapists and families who are already using the experimental programme have reported varying levels of success. Case studies and preliminary trials have shown efficacy and as reported earlier, a division of a US insurance company recently gave its approval to pay for the programme including listening equipment and a therapist's time to oversee its use (ABT, "TLP Military, Tricare," 2017). The present study shows a significant difference between the experimental and the passive control group, in the domains of Social Abilities and Behaviour, and while there was not significant change in the domain Communication, there was a downward trend for improvement. To test the hypothesis that the active control group would show greater improvement than the passive control group but less improvement than the experimental group, mean scores for each group were compared. Results were as predicted, that the children using the experimental programme experienced change that was consistently greater in each domain than the unfiltered structured music listening or no intervention. An additional analysis was run to determine the difference between the active and passive control groups, and the difference was not significant in any domain. While not significant, scores from the AQ Child also showed a downward trend in severity of symptoms, providing additional support for the theory that if auditory sensitivity could be reduced, many symptoms of autism, should also be reduced. Many of these coping behaviours, as described earlier by ASC individuals, are considered common symptoms in autism. Further research that is more targeted in identifying who might best benefit, may provide evidence for significance in the communication domain. Until that time, effects cannot be generalized and some care should be taken in recommending the experimental programme.

In daily family life, even small changes in abilities and behaviours can be life altering. If a parent is seeking relief for their child in the areas of Social Abilities and Behaviours that have been associated with auditory sensitivities, a therapist may suggest the programme, using care to caution the parent that while not all children respond, there is initial evidence showing that if auditory sensitivities are present, the programme may help their child. Until further research can reliably predict characteristics of best responders, clinicians should continue to use their personal experience in recommending usage.

6.0 Summary

This is the first RCT comparing TLP Spectrum, a filtered music listening programme designed for ASC children exhibiting auditory sensitivities, to a similar unfiltered music listening programme and a passive control group. Changes were measured to determine differences between the three groups, and these were significant only in the domain Behaviour. Changes in three domains were also measured to determine any difference between the experimental group and the passive control group with statistically significant improvement shown in Social Abilities and Behaviours and with downward trends for improvement in Communication. Several other elements of the programme were tested. To determine if filtering was an important element that could be associated with change, a similar unfiltered music listening programme was compared. It was predicted that the unfiltered music would create change greater than no intervention but less than the experimental programme and this was shown to be true for each domain. There difference between the active or passive control groups was not significant in any domain. An assessment at 40 weeks was given to determine if any changes might persist, or if change would only occur while listening and while the difference between groups was not significant, change was maintained after a 20 week interval with no listening.

The study is timely, as ASC parents have requested more information about abnormal sensory sensitivities and associated behaviours (Pellicano et al., 2014), issues many caregivers deal with on a daily basis. In addition auditory neuroscience is expanding our knowledge of music and how it affects the brain, and research into sensory sensitivities is gaining a greater understanding of the complex elements contributing to sensory dysfunction. The thesis fills a gap by providing an updated literature review about the extensive use of the many filtered music listening programmes that claim to modify these sensitivities, looks at the science behind the theories and ideas suggested by two of the first creators of filtered music programmes over 50 years ago, and reports on the first RCT with TLP Spectrum. It also provides evidence from auditory neuroscience brain imaging that change does occur in the auditory pathway from listening.

For the RCT, 63 children ages 4 to 8 and diagnosed with ASC were recruited for the study, and randomly assigned to one of the three groups. Participating parents were responsible for overseeing the programme at home. Each parent was provided with a guidelines booklet that included a listening diary. The guidelines explained protocols and gave suggestions for getting started for the two listening groups. A self-selected parent completed four assessments at baseline and 20 weeks, and one as a follow-up at 40 weeks. Forty-four children completed the 20 week protocol, and one more was included who had completed 18 weeks.

Data supported the primary hypothesis in two of the three domains, stating that the experimental group would show a significant difference in the primary measured outcomes as compared to a passive control group over a 20 week listening protocol. The two domains showing significant change were Social Abilities and Behaviours. When comparing the three groups, the unfiltered music listening group showed change greater than no intervention but less than the experimental programme, as predicted in all three domains. A 40 week follow-up assessment was used to determine if any reported changes would be maintained without daily listening for 20 weeks and scores remained relatively stable. Visual examination of the data revealed that a subset of children in both music listening groups showed improvement. A responder was defined in two ways: as greater than one SD or showing statistically significant change and as MCID or showing noticeable change (measured as one half a SD for the domain).

Caution must be given to results due to the small sample size for each group. However, this initial RCT is promising and results support the outcomes of past studies as noted earlier. While the results were not significant in all domains measured, there was a downward trend in the domain Communication and in total scores for the AQ Child in measuring severity of symptoms. The three domains measured by the ATEC and total scores of the AQ child showed a greater effect from the experimental programme with little change seen in the passive control group. Parents of children in the experimental listening group reported significantly lower stress levels at the end of the 20 week protocol compared to the control group with no intervention.

Individual comments by parents who participated added to results found through analyses. Parents wrote they noticed changes in eye contact, improvements in talking, holding longer conversations, greater social interaction, ability to sit and focus for longer periods, and easier transitions. A number of children reported they liked the music in the experimental programme and several asked to listen, two reminding their mothers when it was time. One child in the active control group also asked for their listening times.

Contributing evidence from previous published studies, plus clinical usage of the experimental programme over the past 18 years as reported by professionals, thus suggests that a subset of children should benefit from the programme in specific areas such as Social Abilities and improved Behaviours. Future research should attempt to define the characteristics of best responders and identify patterns of sensory symptoms and their severity that may respond to the filtered music listening programmes.

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Appendix A

Listening Programmes Including Websites and Books

Tomatis Inspired Listening Programmes:

- Tomatis Method: http://www.tomatis.com/

  The Conscious Ear by Alfred A. Tomatis (autobiography)

  Listening for Wellness: An Introduction to the Tomatis Method by Pierre Sollier

- EnListen: www.soundlistening.com (from US)
- Integrated Listening Systems (iLS): http://www.integratedlistening.com/ (from US)
- Listening Fitness Trainer: http://www.listeningfitness.com/ and listeningcentre.com. (from Canada)

  When Listening Comes Alive: A Guide to Effective Learning and Communication by Paul Madaule

- Lollipop Listening: http://soundtherapysystems.com/ (from US)

  Awakening Ashley: Mozart Knocks Autism on its Ear by Sharon Ruben

- Samonas Sound Therapy: http://www.samonas.com/ (from Germany)

  Samonas Sound Therapy: The way to health through sound by Ingo Steinbach

- Sound Therapy International:

  http://www.soundtherapyinternational.com/v3/home.html (from Australia)

  Sound Therapy: Music to Recharge Your Brain by Patricia Joudry and Rafaele Joudry

  Triumph Over Tinnitus by Rafaele Joudry

  Why Aren't I Learning? By Rafaele Joudry

- The Listening Program: http://www.thelisteningprogram.com/, also http://www.advancedbrain.com/ (from US). In the UK: www.learning-solutions.co.uk

  Healing at the Speed of Sound by Don Campbell and Alex Doman

  I Believe in You: A Mother & Daughter's Special Journey by Michele Gianetti, R.N.

  Cutting Edge Therapies for Autism, Fourth Edition by Ken Siri and Tony Lyons (Chapter 64: The Listening Program: An Effective Treatment for Autism by Alex Doman, p 498-504)
- Learning Ears: http://moyerslearningsystems.com/home.html (from US)

  Uses The Listening Program and adds active voice training with specialized instruction for reading and spelling skills.
- Therapeutic Listening/Vital Links: http://www.vitallinks.net/ (from US)

Books containing information about several methods:

- *Sound Bodies through Sound Therapy* by Dorinne S Davis
- *Every Day a Miracle: Success Stories with Sound Therapy* by Dorinne S. Davis and Ruth Cruz

Berard AIT Inspired Listening Programmes:

- Berard AIT: http://berardaitwebsite.com/ and www.aitinstitute.org

  Dr. Guy Berard: http://www.drguyberard.com/

  Hearing Equals Behavior by Guy Berard, original French title is *Audition egale comportement.*

The Sound of a Miracle: The Inspiring True Story of a Mother's Fight to Free her Child from Autism by Annabel Stehli

Dancing in the Rain: Stories of Exceptional Progress by Parents of Children with Special Needs by Annabel Stehli

The Sound of Falling Snow: Stories of Recovery from Autism and Related Disorders byAnnabel Stehli

Cutting Edge Therapies for Autism, Fourth Edition by Ken Siri and Tony Lyons (Chapter 69: Berard Auditory Integration Training by Sally Brockett, p 537-542)

- Digital Auditory Aerobics (DAA): www.lifeskillscenter.com/digital-auditory-aerobics-daa/ DAA is a version of Auditory Integration Training
- Kirby Method of Auditory Integration Training: http://www.kirbyait.com/index.html
  Uses the Kirby Auditory Modulation System
- Filtered Sound Training, PC-Personalised Auditory Training System: www.filteredsoundtraining.com
- Electronic Auditory Stimulation effect. EASe: https://vision-play.com Inspired by Berard AIT.

Appendix B

TLP Spectrum Provider Reference Document

Introduction

Sound is everywhere. It is as much a part of our lives as the air we breathe, and the food we eat. It's important for all of us to feel comfortable in our sound environment in order to fully enjoy and participate in all that life has to offer. TLP Spectrum™ was developed to create or restore a positive relationship with sound.

TLP Spectrum provides sound support for everyone, and can be particularly beneficial to children and adults with sensory sensitivities, helping them to become more comfortable in their environment, better able to self regulate, understand, respond to, and benefit from information coming through their senses.

Many sensory sensitive people are particularly reactive to sound. They may not be able to tolerate certain sounds and are considered to have auditory hypersensitivities. Often, when people are overly sensitive to sound they are also hypersensitive to other sensations including touch, movement, visual stimulation and even taste and smell. Interestingly, those who have hypersensitivities sometimes also have hyposensitivities, or less-than-typical sensitivity to sensory input. While certain stimulation may be fear-inducing, bothersome or irritating, other types of stimulation are craved or sought or not even at a level of awareness. Difficulty with sensory sensitivity can have an extreme affect on daily life.

Many people who are sensory sensitive live in a steady state of "fight/flight". The body's survival mechanism, this protective reaction is an acute response to stress. While fight/flight is a necessary biological function, it is unhealthy to remain in this state given it raises stress hormones, lowers immune function, slows digestion, reduces bladder and bowel control, increases heart rate, deceases peripheral vision, and impacts the ability to sleep. Its far reaching negative effects impact health, social engagement, listening, communication, learning and performance.

Researchers are investigating various mechanisms that may contribute to auditory hypersensitivity. One of the mechanisms is a deficit in modulating or “gating” sensory information. Gating relates to the proper neural “decision making” to allow some sensory information to pass from lower levels to higher levels in the central nervous system. The gating mechanisms help “filter out” unwanted, unnecessary sound so that we can get only what is critical and important to the higher cortical levels where we comprehend and understand what is heard. This involves the classical auditory system and its ascending and descending pathways. TLP Spectrum may contribute to improving sensory gating.

Another mechanism of auditory hypersensitivity involves the non-classical auditory system and an emotional response to sound rather than an auditory response. People described as being hypersensitive to sound have negative emotional reactions to sounds and to situations in which the sounds are present. It is possible to desensitize these negative emotional reactions and reprogram the emotional memory system with TLP Spectrum so that certain sounds and/or the anticipation of those sounds are no longer associated with fear or discomfort.

TLP Spectrum offers all the benefits you have come to expect with The Listening Program® and is ideal for helping people establish a healthy relationship with sound. It incorporates the extensive use of music with low frequency sounds which provide grounding and add to a sense of calm. These sounds support functions including rhythm, balance, coordination, motor skills, body awareness, and self regulation. TLP Spectrum is the ideal choice for those with; autism spectrum disorders, sensory processing disorder, brain injury, developmental delays, and for those needing to improve motor and coordination problems. It is also an excellent choice for neurotypical toddlers, preschoolers, and the elderly.

Key Information

TLP Spectrum™ is a highly specialized program developed as the primary listening training for people with sensory sensitivities.

It introduces new music and neuroacoustic processing, a graduated listening sequence, and extensive use of calming low frequency sounds.

The foundation is original High Definition recordings of Classical music performed by the award- winning members of the Arcangelos Chamber Ensemble. The music is enhanced by ABT’s Spatial Surround® production process and Dolby Headphone® audio encoding. These technologies are optimized to develop the listener’s awareness of his/her spatial environment. Newly created Active Listening Training™ also helps develop awareness of and comfort with sound in space (see below).

The listening sequence includes frequent, incremental changes in training intensity of sound frequency, volume dynamics, and spatial training in a refined sequence occurring throughout each week. This is a result of years of experience with TLP Level One. It provides the just right level of training challenge and sufficient novelty to stimulate brain plasticity with balanced sound input. TLP Spectrum is expected to be the ABT program-of-choice for people who are sensory sensitive. Once this program is completed, listeners can move on to TLP Level One, which builds on the solid foundation provided by TLP Spectrum. Note there are no nature sounds in TLP Spectrum.

TLP Spectrum is available in two system options; iPod nano with the ABT Bone Conduction Audio System™ or with ABT approved air conduction headphones. Each comes with the 200 module spectrum program, 4 preparatory modules for headphone training, and a TLP handbook.

Training Progression

TLP Spectrum™ includes 200 modules in the Blue, Green, Orange, and Red treatment zones.

Zone	Filter	Music Frequency Focus
Blue	Unfiltered	full/ 20 Hz-20 kHz
Green	low-pass	low/ 20 Hz- 1.5 kHz
Orange	band-pass	mid/ 500 Hz- 5 kHz
Red	high-pass	mid-high/ 750 Hz - 20 kHz

The training progression guides the listener through the following sequence.

Cycles 1 & 2		Cycles 3 & 4	
Zone	Modules	Zone	Modules
Blue	001-020	Green/Red	200-151
Green	021-060	Green/Orange	150-061
Green/Orange	061-150	Green	060-021
Green/Red	151-200	Blue	020-001

Different levels of filtration and spatial processing are introduced as the listener progresses, gradually increasing intensity through each zone. Note that cross training is introduced so the listener is supported with music incorporating low-pass filters in the Green zone when training in Orange and Red, providing supportive low frequency sound though all portions of the program that present filtered music.

The TLP Spectrum protocol should be followed for at least two cycles (50 hours) and up to four (100 hours), using the Extended, Base or Condensed schedules. It also will serve well as a maintenance protocol to support the long term needs of people with sensory sensitivities. Program modifications, when needed, can be made by decreasing or increasing training duration within any zone.

Listening logs are available on the Advanced Brain Technologies website at advancedbrain.com.

Neuroacoustic Processing

Music The musical foundation of each module is original, High Definition recordings of beautiful and pleasing Classical music with compositions from Mozart, Haydn, Vivaldi and Danzi performed by the award-winning members of the Arcangelos Chamber Ensemble.

ABC Modular Design™ Each module follows Advanced Brain Technologies exclusive ABC modular progression, which takes the listener through multiple levels of sound training in 15 minutes.

The modules include seamless tempo entrainment, and transitions within musical complexity, spatial training, frequency focus, and volume dynamics which move through a sequence of low- moderate-high-moderate-low intensity training, providing a balance of stimulation and grounding to support self-regulation.

Active Listening Training™ (ALT) Active Listening Training™ is introduced in TLP Spectrum™. This process is exclusive to The Listening Program® and was created to improve attention, frequency and volume discrimination, spatial awareness and sound localization.

ALT eases people into listening by using a spotlighting technique to bring attention to one instrument in the 360 degree spatial field for short durations of time, then progressively spotlighting others through changes in instrument volume and timing throughout the module. This offers a constant spatial reference to help the listener better understand his/her position in time and space, and serves as the foundation of the spatial progression in TLP Spectrum.

ALT modules include no filters, audio bursting, or Spatial Surround® Dynamics, making them the ideal beginning of the TLP Spectrum program.

Active Listening Training Sweeps™ (ALT-S)Also exclusive to The Listening Program® Active Listening Training Sweeps™ build on the ALT process, by adding filtered music to the module.

There are two types of ALT-S modules. The first gradually sweeps from full spectrum, to filtered, back to full spectrum music over the course of an entire module. The second type sweeps over the course of each of the three, five minute phases within the module. Active Listening Training Sweeps provide the listener with a gradual introduction to filtered music. At each point in the program a new level of filtered music is introduced, it is done through ALT-S modules.

ALT-S modules include no audio bursting or Spatial Surround® Dynamics.

Appendix C

Autism Listening Study: Parental Permission and Loan of Equipment

THE UNIVERSITY *of* EDINBURGH

Autism Listening Study: Parental Permission

I understand that the autism listening study will continue for 40 weeks. I understand that my child may not receive the programme in the first 20 weeks. As part of the study design, my family will be randomly allocated to one of three groups: a control group with no listening, a group listening to classical music, or a group listening to filtered and modified classical music. If my child is not in a group that has been allocated the listening programme, he/she will be receive it after the study is completed at 40 weeks. I have the right to withdraw my child from the study at any time. I understand that I will be responsible for completing assessments before the study begins, after it ends, plus a brief weekly assessment. After completing the initial assessments, I will be given listening equipment on loan for the study, to be returned when the study ends.

I give my permission for ______________________________ ____________________
(child's name) (child's age, birth date, year)
to participate in the autism listening study. My child was diagnosed with Autistic Spectrum Disorder, ASD, by

______________________________ ____________________
(Professional's name & title such as MD, Clinical Psychologist) (Approximate Date)
I confirm that my child does not have other major medical diagnoses.

____
(Parent's Name – Please Print)

____
(Parent's Signature)

____
(Address)

____
(City) (Postal Code)

Email: ______________________________

Phone 1: ____________________ Phone 2: ____________________

Number of other children in your family and ages:

____

Please complete, sign, and return this form to:

Dorothy Lawrence, Research PhD student
School of Health in Social Science
The University of Edinburgh
Medical School, Doorway 6
Teviot Place
Edinburgh, EH8 9AG

Email: D.K.Lawrence@sms.ed.ac.uk

SCHOOL *of* HEALTH IN SOCIAL SCIENCE
Section of Clinical & Health Psychology
The University of Edinburgh
Medical School
Teviot Place
Edinburgh EH8 9AG
E-mail : D.K.Lawrence@sms.ed.ac.uk

University of Edinburgh Terms and Conditions relating to Loan of Equipment for the Student Project, the Autism Listening Study to Improve Social Behaviours.

The Apple iPod, preloaded music programme, air/bone conduction headphones and amplifiers loaned for the purpose of this study remain the property of ABT, are loaned through the University of Edinburgh and must be returned to the University at the end of the study period without exception. The University reserves the right to request the return of this property at any time prior to the pre agreed date.

All reasonable efforts should be made to maintain it and keep it in good working order. This equipment is loaned expressly and solely for the purpose of using the programme as outlined and it's use should be limited solely to listening to the programme with the supplied headphones only. No attempt should be made to alter or remove the preloaded iPod content.

Please note that attempting to download additional data into the iPod may damage the preloaded programme and the hardware, and will be considered a deliberate breach of these terms and conditions of loan. If this occurs you may be liable for the cost of repair or replacement.

The University of Edinburgh is not responsible for any content on the iPod, which has been supplied by ABT for the purpose of the study, but has made every reasonable effort to ensure that the device cannot be used for any other purpose.

The University will not hold participants responsible for reasonable wear and tear or accidental damage to the equipment. However, if we have reason to believe that the equipment has been maliciously tampered with or broken deliberately we may seek to recover the cost of the damage of the equipment.

The University is entering into this trial in good faith that the conditions and guidelines outlined for participation are adhered to.

Declaration: ***I have read and I accept these terms and conditions.***

Signed: ______________________________

Print Name: ______________________________

Date: ____________________

iPod Serial Number: ______________

Appendix D

Section of Clinical Psychology Ethics Research Approval Letter

Department of Clinical Psychology
School of Health in Social Science

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891

Dorothy Lawrence
10 / 9 Boat Green
Edinburgh
EH3 5LL

14th March 2013

Dear Dorothy,

Re: 'An Investigation into the Efficacy of Using a Filtered Music Programme to Improve Social Engagement Behaviours Found in Autistic Spectrum Disorder'
Application for Level 2-3 Approval

Thank you for submitting the above research project for review by the Section of Clinical Psychology Ethics Research Panel. I can confirm that the submission has been independently reviewed and was approved on the 20th December 2012. Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

Kirsty Gardner
Senior Secretary

Appendix E

Autism Listening Study Website: www.autistmlisteningstudy.com, 4 pages

autismlisteningstudy

An autism intervention you can use at home for children aged 4 to 8

An Autism Listening Study

Children with autistic spectrum disorder (ASD) experience difficulties with communication, social interaction, and appropriate behaviours. Processing and understanding auditory information is often considered to be a crucial aspect of such difficulties. This 40 week study will test a filtered music listening programme, to determine whether regular listening habits can create positive changes in a child's ability to engage socially.

Over a dozen music listening programmes are advertised on the internet, claiming to provide specific stimulation that trains the brain to process sound more accurately. These interventions vary in many ways, including theoretical bases, type of music used, modifications made to the music, and listening protocols. Some of the programmes have preliminary studies that show promise for treating autism and auditory processing difficulties, but few have reliable, scientifically based research to support their claims.

My study will determine if the programme I've selected is effective in improving aspects of social engagement. This will help to provide more accurate information about music listening programmes for parents, educators, and health care professionals.

You are invited to participate in this study if you are a parent with a child aged 4 to 8 years diagnosed with autism, and live in the UK. The study is part of my PhD in Clinical Psychology at the University of Edinburgh.

autismlisteningstudy

An autism intervention you can use at home for children aged 4 to 8

Who Can Participate?

- Does your child have an official diagnosis of Autistic Spectrum Disorder (ASD)? This includes Aspergers and PDD-NOS.
- Is your child between the ages of 4 and 8 years?
- Can your child wear headphones? Most children can, even with sensitivities to sound and touch.
- Can you keep notes and report your observations in English?

If you have answered *"yes"* to all these questions you and your child are eligible to participate. NOTE: Children who have a diagnosis of ASD with a major medical diagnosis such as Down's or tuberous sclerosis unfortunately do not qualify for this study.

The study takes place entirely in your own home. It will last for 40 weeks (10 months). As part of the study design, families will be randomly allocated to one of three groups: a control group with no listening, or to one of two different music listening programmes, which are being compared.

Families in the music listening groups will be loaned equipment for use during the study. Your child will listen through special headphones 30 minutes per day, from Monday to Friday, with a weekend break. If your child is not given the selected music programme during the study itself, he/she will be provided with it after the study is completed at 40 weeks. This study design will inform us as to whether the intervention is really creating measurable change.

If you are interested in taking part, you will need to give written permission for your child to participate and sign a waiver that says you understand the equipment is on loan and must be returned to the University at the end of the study. All personal or family information is confidential and no identifiable information will be used in any public materials. Only anonymous data will be retained after the end of the study.

autismlisteningstudy

An autism intervention you can use at home for children aged 4 to 8

Assessments for the Study

All parents will complete four simple assessments that can be done at home and are estimated to take one to two hours to complete all four. These will be completed once before starting and once after completing the first 20 weeks of the study. One of the shorter assessments will also be completed weekly during the first 20 weeks and later at 30 and 40 weeks to see if any further changes have occurred. The four assessments will let us know if change has occurred during this time in the following areas:

- the severity of your child's autism
- his/her abilities in communication, daily living skills, and ability to socialize
- your stress levels as parents.

If you are in one of the two music listening groups, we will also ask you to keep a simple weekly diary noting the two modules your child listens to daily and any unusual events during the week, such as grandparents visiting that week, for example.

Once accepted for the study, all families will complete four required assessments before the study begins and at the end of the 20 week period. All families will also complete a short weekly assessment for the first 20 weeks, then at 30 and 40 weeks. All families will receive an instruction booklet and the two music listening groups will then be given equipment and a listening diary. After 40 weeks, the selected listening programme will be given to all families who did not receive it initially.

The booklet of listening instructions will give you ideas on getting started including wearing headphones, establishing a daily routine, and suggested activities your child might engage in while listening. It will also include instructions for using the listening equipment.

NOTE: Whilst the study is ongoing, we ask you not to engage in other intensive interventions, so we can determine if this particular programme is effective.

Enrollment is Now Closed | autismlisteningstudy https://autismlisteningstudy.com/how-to-enrol/

autismlisteningstudy

An autism intervention you can use at home for children aged 4 to 8

Enrollment is Now Closed

Here's how to enrol. Send me an email with your child's age, if they have had an official diagnosis of ASD, your name, and how to contact you.

Email me at: D.K.Lawrence@sms.ed.ac.uk

Please share this site with other parents of children diagnosed with ASD and encourage them to participate. The more children who experience the intervention, the more data we will have to determine if the intervention is effective, and if it is, what changes parents might expect to see.

About Me

My name is Dorothy Lawrence and I am a Research PhD student at the University of Edinburgh in Clinical Psychology. I'm interested in the idea that sound can stimulate parts of our nervous system to make it work more effectively, as proposed by Dr. Stephen Porges in his theory of social engagement. I want to see if 30 minutes per day of listening at home to the selected programme, creates positive changes in behaviours and function in children with autism, anywhere on the spectrum.

1 of 2 2/17/17, 2:04 PM

Appendix F: Autism Listening Study Brochure

About Me

My name is Dorothy Lawrence and I am a Research PhD student in Clinical Psychology at the University of Edinburgh.

I've designed a randomized, controlled study to test a filtered music listening programme that is currently available through trained professionals. I want to see if 30 minutes per day of listening at home to the selected programme, creates positive changes in behaviours and function in children with autism, anywhere on the spectrum.

The programme is based on the idea that sound can stimulate parts of our nervous system to make it work more effectively, and that the way in which sound is processed in the brain can improve with practice.

Changes may include

- an increase in communication,
- improved social interaction,
- more normal behaviours and
- improvement in daily function.

Participate in Research

THE UNIVERSITY of EDINBURGH

This study contributes to psychology research being carried out at the University of Edinburgh, UK. Your participation helps researchers learn more about improving social function and behaviours in children with Autistic Spectrum Disorder.

Supervisors:
Prof. Matthias Schwannauer, Head of Clinical Psychology
Dr. Katie Overy, Senior Lecturer, in Music

For further information about this study or to enrol, please contact me:

Email: D.K.Lawrence@sms.ed.ac.uk

Phone: 0776 819 6913 (leave a message)

www.autismlisteningstudy.com

Autism Listening Study

Testing A Filtered Music Listening Programme

For Ages 4 to 8

Can my child participate?

Does your child have an official diagnosis of Autistic Spectrum Disorder? This includes Asperger's and PDD-NOS.
Is your child between the ages of 4 and 8 years?
Can your child wear headphones? Most children can, even with sensitivities to sound and touch.
Can you keep notes and report your observations in English?

If you have answered "yes" to all these questions, you and your child are eligible to participate! NOTE: Children who have a diagnosis of ASD with a major medical diagnosis such as Down's or tuberous sclerosis do not qualify for this study.

If you find this information interesting, please share it with other parents of children diagnosed with ASD and encourage them to take part.

The more children who experience the therapy, the more data we will have to determine if the therapy is effective, and if it is effective, what changes parents might expect to see.

What would I need to do?

The study will take place entirely in your own home. It will last for 40 weeks (10 months) with 30 minutes of daily listening, 5 days per week, for a 20 week period.

As part of the study design, families will be randomly allocated to one of three groups: a control group with no listening, or one of two groups with different music listening programmes, which are being compared.

If your child is not in a group that has been allocated the selected music programme, he/she will receive it after the study is completed at 40 weeks. This study design will help to inform us as to whether the intervention is really creating measurable change.

All parents will need to complete several assessments before the study begins and after the study ends. All the assessments can be done at home and are short and simple to complete.

Listening equipment will be provided on loan for the study. All participants will be given a brief summary of the results when it is complete.

NOTE: While the study is on-going, we ask you not to engage in other intensive interventions so we can determine if this particular programme is effective.

How will the research be used?

Over a dozen music listening programmes are advertised on the internet, some mostly in the UK, Canada and Australia, others only in the US. They claim to provide specific stimulation that trains the brain to process sound more accurately.

The programmes vary in many ways. Some have preliminary studies that show promise for treating ASD, but very few have reliable, scientifically based research that supports their claims.

My goal as a researcher is to determine if the listening programme I've selected creates positive change in the core features of ASD, that is, in a child's ability to engage socially with others.

The programme claims to address quality of life goals that make an important difference in family life and can be used with very young children as well as adults. I want to provide parents, educators, and health care providers with accurate, evidence-based information about this programme and about filtered music listening interventions.

Appendix G: Autism Listening Study Poster

Autism Listening Study

Testing a Filtered Music Listening Programme
For Children Diagnosed with ASD

Can my child participate?

- Does your child have an official diagnosis of Autistic Spectrum Disorder, ASD? This includes Asperger's and PDD-NOS.
- Is your child between the ages of 4 and 8 years?
- Can your child wear headphones?
- Can you keep notes and report observations in English?

If you have answered "***yes***" to all these questions, you and your child are eligible to participate. NOTE: Children who have a diagnosis of ASD with a major medical diagnosis such as Down's or tuberous sclerosis unfortunately do not qualify for this study.

What would I need to do?

Your child will listen to music through headphones at home, 30 minutes per day, for 5 days per week. You select the time of day that best fits your family's schedule. The study will last for 40 weeks (10 months). You will complete several assessments and keep a very simple weekly diary. Whilst the study is ongoing, we ask you not to engage in other intensive therapies so we can determine if this programme is effective in improving features of social engagement.

How will the research be used?

Many different music listening programmes are advertised on the Internet as helpful for ASD, but they often do not have reliable, scientifically based research to show if they really do work. This study will test one of them so that parents and health care professionals can have accurate information.

About me

I am a Research PhD student in Clinical Psychology at the University of Edinburgh. My name is Dorothy Lawrence and I've designed a randomized, controlled experiment to test a currently available listening programme. I want to know if listening will create positive behavioural changes in children with ASD. These changes may include an increase in communication, more normal social behaviours, and improvement in daily life skills.

THE UNIVERSITY *of* EDINBURGH

Further information, including how to enrol, can be found at:

Email: D.K.Lawrence@sms.ed.ac.uk

Phone: **0776 819 6911** (leave a message)

Website: www.autismlisteningstudy.com

Appendix H

Guidelines and Instructions

for the Autism Listening Study

Welcome and thank you for your interest in participating. Please take the time to read the guidelines and instructions for the study. This booklet will help you to understand how to get your child started with the music listening programmes, how we will measure any change in your child's behaviour, and useful tips and guidelines concerning the programmes and the equipment.

Assessments - Measuring Change

Four assessments have been chosen to measure possible changes you and your child may experience with the listening programmes. They are all questionnaires with simple rating scales that you as a parent, will complete at home. It will probably take between one and two hours total time to complete all four assessments.

The parent who is the primary caregiver should complete all the assessments. This is the parent who would know how their child responds to siblings and other children, the child's eating habits, the number of meltdowns during the day, sleeping habits, and so forth.

The four assessments should all be completed on the same day, by the same person, and preferably at the same time. It is important to set aside 1-2 hours in a quiet space, perhaps after your child/children are in bed and settled for the night. If something unexpected happens and you are unable to finish all four, please complete the remaining assessments as soon as possible and definitely within that week.

Write the number assigned to your family on the form, and the date. Indicate who is completing the assessment.

Take your time to think about the questions and to give your answers. Some days are better than others for your child. Try to think of your child's general behaviour over the past several weeks when you complete the forms. Tick the response for each item that most accurately describes your child. For the Autism Parenting Stress Index, you will be assessing your own stress levels and concerns about your child's health and welfare.

You will only need to complete all four assessments before you start the listening programme and at 20 weeks when listening ends. At 30 and 40 weeks, you will complete just one assessment, the ATEC, which will also be completed weekly online. These "follow up" assessments at 30 and 40 weeks will allow us to see if any changes have maintained and if any improvements continue after the listening programmes are completed. Please answer the questions as thoughtfully as you can, since this will record an accurate picture of any change in function and behaviours that have occurred during the 40 week time frame for the study.

Three of the assessments can be completed online. An envelope has been provided so that when the Vineland (a paper booklet) has been completed, you can return it to the investigator at the University.

Dorothy Lawrence, Research PhD student

Clinical Psychology, School of Health in Social Science

The University of Edinburgh

Medical School, Doorway 6

Teviot Place

Edinburgh, EH8 9AG

Email: D.K.Lawrence@sms.ed.ac.uk

Below is information about each assessment along with an estimated time for completion.

AQ-Child, Cambridge Autism Spectrum Quotient: Children's Version

Estimated time to complete: approximately 15 minutes

The AQ-Child, Cambridge Autism Spectrum Quotient Children's Version is also titled The Cambridge University Behaviour and Personality Questionnaire for Children. It has 50 items and is designed to measure the degree to which a child has traits that are typical of ASD in children aged 4 to 11 years old. You will click on responses on a scale that tells how severe a particular trait is for your child. These will range from "definitely agree" to "definitely disagree." This will help us to understand where your child may be within the spectrum of autistic traits.

https://www.survey.ed.ac.uk/aq-pre

VABS-II, Vineland Adaptive Behaviour Scales, 2nd Edition

Estimated time to complete: 20 to 60 minutes.

The VABS-II is a formal assessment that is often used to measure how well a treatment creates change. It is designed to assess everyday functions in communication, daily living skills, socialisation, motor skills, and maladaptive behaviours. This is a paper booklet that has been posted to you. Please note that each section has a starting point for the age of your child. If the first section says "Start Ages 0-4" and your child is 6, skip these questions and begin where it says "Start Ages 5+." Remember to keep going after the start point for your child's age, to the end of each section.

ATEC, Autism Treatment Evaluation Checklist

Estimated time to complete: 10 minutes

Autism researchers developed the ATEC to assess treatments already available for ASD, to provide information for parents on what treatments might really create change for their child. It has been used for a wide variety of treatments and is useful as a quick, easy general summary of behaviours and skills.

https://www.survey.ed.ac.uk/atec-pre

Weekly ATEC: The developers of the ATEC say it is simple enough to be used weekly. In addition to before and after the listening study, you will receive an email each Friday with a link so we can get a general idea of when any changes might occur. This will add to our information about the programmes. There are always good days and bad days, good weeks and bad weeks. Don't worry about what you ticked the week before. Just do the best you can to think about the past week and tick the boxes that apply. If for some reason you miss a week, simply complete the assessment sent to you on that Friday, assessing any changes over the past two weeks. The number of the ATEC, such as ATEC-5, should be completed at the end of the 5th week of listening, and so on.

APSI, Autism Parenting Stress Index

Estimated time to complete: approximately 5 minutes

This index measures aspects of your child's health and behaviours that may be causing stress to you and/or your family. Simply click on the answer that best describes your situation.

https://www.survey.ed.ac.uk/apsi-pre

How To Use the Equipment

Provided for the Autism Listening Study

A short video explains step-by-step how to use the air/bone conduction headphones and amplifier. It can be found at www.autismlisteningstudy.com in the section, "For Participants Only." Use the word **"spectrum"** as the password for access. Instructions are also written out and given below for your reference.

iPod loaded with the music programmes

The iPod contains 200 modules of music for the 20 week listening period. Your child will listen for 30 minutes per day to two 15 minutes modules, or 10 modules per week for 20 weeks.

Using the iPod:

- The 6 inch (15.24 cm) connection cable should be connected from the "IN" port on the headphone amplifier to your iPod.
- To turn the iPod on, press the "ON" button on the top right of the iPod.
- Select the correct album from the playlist for the day. If you start with module number 1, the next module, number 2, comes up automatically when the listening session ends, then number 3, and so on. Your child will listen to two 15 minute modules each day. The daily numbers are given in your Listening Diary. You should be able to simply turn on the iPod and press play. Instructions for volume control are given below. If you need to adjust the volume, you should do this on the amplifier only, not on the iPod.
- At the end of each 15 minute module, an audio cue (a voice saying "this module is now complete") will indicate when the module is finished.

Headphones and amplifier

Air/bone conduction headphones conduct sound to the inner ear through the bones of the skull as well as through the air. That is the way you hear your own voice and why a recording of your own voice always sounds different. There is a round flat vibrator built into the headphones that sits on the top of the head. The headphones for the autism listening study are designed for both air and bone conduction.

The listening equipment should be connected when you receive it. However, if anything comes unplugged, here's how to reconnect the cords and amplifier.

There are three ports at the top of the amplifier: IN, AC and BC.

- Connect the 6 inch/15.24 cm connection cable from the headphone port on your iPod to the "IN" port on the headphone amplifier
- Connect the mono headphone cable (one black line) to the "BC" port (bone conduction port) on the amplifier.
- Connect the stereo headphone cable (two black lines plus blue ring) to the "AC" port (air conduction port) on the amplifier.

Settings for the iPod and amplifier:

- On the iPod, volume should be set at 80 to 100% of capacity and should remain at this setting.
- Power the amplifier ON/OFF by pressing and holding the power button until you see the words "powering on" or "powering off" on the display.
- Press the Select button for the menu.
- Air conduction or AC will light up. This menu controls channel balance and volume. The channel balance should be in the middle and should stay in this position. You can adjust the listening volume by pressing the right arrow to increase volume and the left arrow to decrease volume. <u>This is the only place where you should adjust the volume level.</u>
- Press the Select button again for bone conduction
- Bone conduction or BC will light up. The volume/vibration level will be set at 5 and should remain at this level.
- When you press the power button for OFF, the settings are always saved.

Helpful Tips

1. Review the instructional video for detailed instructions on using the air/ bone conduction equipment. You will learn the correct configuration and setup, how to adjust your settings, and how to avoid potential problems.

2. Charge your iPod when it shows less than 50% charge. Plug and unplug your AC charger carefully. Make sure all connections are secure.

3. Do not connect your study iPod to a computer. Do not attempt to sync your autism listening study iPod to iTunes as you will lose the music files for the study!

4. The headphone amplifier uses AA alkaline batteries, which will generally last for about 10+ hours. Power your amplifier OFF when not in use to conserve battery life. You may need to put in new batteries every 10-15 hours of listening.

5. The battery compartment is in the back of the amplifier. Slide the compartment open with your thumb. There are minus and plus signs for the batteries. Slip in the batteries with the positive ends matching the signs in the compartment. Do not use rechargeable batteries. You have been given 4 boxes with 10 batteries in each box, to help you to easily follow the protocols. These batteries should last for the 20 week listening period.

Getting Started with Daily Listening

ESTABLISHING A ROUTINE

The **first two weeks will be the most important** part of the listening study. Why? This is the time you will **establish a routine** for your child's daily listening that works for them and for the rest of the family. If you can make daily listening a pleasant habit, the remainder of your time in the study will be easy!

Find a time in your own schedule and your child's daily activities' schedule that you feel you can comfortably make a time for listening. Your goal will be to establish a daily listening session that will become a normal part of your day for the next 20 weeks.

The best times are **before school, after school, or before bedtime**. Before school may be just before or after breakfast but not while eating as chewing will interfere with hearing the programme clearly. Some children find the music relaxing, and bedtime works well as they will easily fall asleep after listening. Others find the music energizing and become too active after listening possibly even interfering with getting to sleep, so evenings or bedtime do not work. You may need to experiment for the first week or two, to see what fits best. When you have found the best time, use this same time daily for the remainder of the study.

Your child will listen to **two 15 minute modules lasting a total of 30 minutes per day, Monday through Friday, five consecutive days**. Your child will listen to each module in the numbered order: numbers 1 and 2 on day one, numbers 3 and 4 on day two, and so forth. Your listening diary shows the correct schedule.

Create your child's first listening experience in a place in your home that they know well, a safe and supporting environment. **Find a place that is quiet** and apart from other family activities, with minimal distractions, and where your child feels calm and comfortable. This may be a play area on the floor or a table where your child spends quiet time with arts and crafts activities or playing with small toys.

APPROVED ACTIVITIES WHILE LISTENING

Create a box of listening activities so that you can take out the box and the listening equipment at the same time. The main idea to keep in mind is that your child should be actively listening to the music. But this doesn't mean they have to just sit. There are many activities they can do to stay contented and engaged.

Select toys and craft items that your child enjoys. The box might include:

- Colouring, drawing and/or painting supplies plus paper, beadwork projects
- Puzzles, blocks, Play-Doh, Lego
- Small toys that children can grasp with their hands, such as small cars and trucks, dolls, stuffed toys, action characters, and so forth. These are toys that can be played with on a table or on the floor in your designated quiet play area.

The only things that should not be done during this time are those taking all the attention away from listening, such as watching television, video games, homework, reading, writing, computer time, and so forth.

Before your first listening session, watch the short video on the autism listening study website (www.autismlisteningstudy.com) in the section participants only (the password is "spectrum"). The video shows you how to use the air/bone conduction headphones and amplifier. You will learn the correct configuration and setup, how to adjust the settings, and how to avoid potential problems. For reference, there is also information in this document with instructions about using the listening equipment.

IDEAS FOR THE FIRST LISTENING EXPERIENCE

Here are some **ideas for the very first listening experience**. If your child has never worn headphones and you are unsure of how your child might react, be aware that your attitude will affect your child. They will feel your anxiety, so begin with confidence!

Wear the headphones yourself to show your child that the headphones are safe and fun to wear. The rest of the family may already wear headphones, which models the experience. **Check that the volume is at a comfortable level** before each listening session.

If your child is hesitant, you may want to let them explore the iPod and headphones. Hand the headphones to your child and guide them to their head, or let your child put the headphones on themselves. If your child is especially hesitant, you may want to plug the headphones into another device that has their favourite music or stories on it. This may provide extra motivation for them to listen and to become used to the headphones. Then you can introduce them to the music listening programme.

If you have a smaller child, you may want to hold and cuddle your child on your lap the first time you put the headphones on. Or if your child is easily absorbed with items in their listening box of toys, get them interested first, then quietly put on the headphones while they are playing. **Set a timer so you know when the sessions end**, at 15 or 30 minutes.

Your child will require monitoring throughout the programme and particularly the first two weeks to ensure headphones are kept on. Occasionally a child may take the headphones off in the beginning. There may be several reasons.

1. The volume may be too loud. That is why we ask you to always check the volume level first. Be sure there is a good connection to the bone conduction amplifier and the iPod and that the level is low. Watch your child's expression and use that to guide you.

2. **Wearing headphones is a new experience**. Children often love the music and adjust quickly. But if they are especially sensitive, you may need to start with only 5 minutes the first time and build up to two 15 minute listening segments or occasionally if it works well for your child and your family schedule, one 30 minute session daily. A 30 minute session may be too long for your child. Their comfort is important, so let that be your guide.

3. Your child isn't feeling well. If your child has a cold and a stuffy head and nose, listening through headphones may be uncomfortable. If you suspect otitis media, **glue ear**, take your child to the doctor and **take a break** from listening until their ears are clear and hearing is normal again. Stuffy ears can make listening uncomfortable and may distort sound.

4. **Your child might be acting out to get attention.** If your child tends to always put off doing things, perhaps always saying they have to go to the toilet, be sure you **take them to the toilet**

before putting on the headphones. If this is their personality, learn to work around it. Give your child something to do with their hands so they won't be free to take the headphones off. As they begin to be comfortable with headphones and start to enjoy the music, this behaviour is very likely to subside.

It is likely that your child will be able to listen for 15 minutes the first time they put on the headphones if they are engaged in items in their activity box. Occasionally a child will be comfortable with 30 minutes the first time but with small children, 15 minutes is more likely and usually the best option. Others who are especially sensitive, my not be able to listen to more than three or five minutes the first time. This is why we ask you to try listening with your child before you actually start the study on a Monday.

What can you do if your child is having difficulties?

IF NEEDED, BUILD LISTENING TIME WITH MODULE ONE

If your child is especially sensitive and can only listen for three to five minutes the first time, **build their listening time with module 1**. Try again later with the same music, continuing to use module number 1. Every day, twice a day, listen to module 1 for 5 minutes as often as necessary, then 10 minutes, and build up to your first 15 minute listening session with module number 1. This will usually not take longer than one week, but may occasionally take two weeks. When your child is able to listen to the complete module number 1 - for the full 15 minutes - they are ready to start the study on the following Monday.

Other Ideas For Tender Ears: If your child is especially sensitive to hats, touching their head, and washing their hair, here are some suggestions. It may take a session of putting on and taking off the headphones many times. Parents wearing headphones and enjoying the music helps the child to see that wearing headphones will be fine. Another useful tool for children who understand the concept, is to say "When you put on the headphones, then we can play with the blocks" or whatever they may especially enjoy doing. The following websites and others may provide additional help for tender ears.

www.sensory-processing-disorder.com

http://www.childrensdisabilities.info/sensory_integration/activities-tactile.html

Practice listening with headphones as often as needed. **Then start on the following Monday with Module number 1** as the first listening session and number 2 as the second session. On Tuesday listen to module number 3 and number 4, and so on through to number 200 at 20 weeks. Generally small children do best with two separate 15 minute sessions rather than one 30 minute session. But this is your choice, and depends on your child's preference and the family schedule. Once a daily routine is established, your child will usually enjoy their daily listening time. If this is not the case, it is up to you to decide whether or not you want to continue to be part of the study. Use the Parent's Listening Diary to track your daily listening sessions. Tick the boxes for the sessions your child completes and note the listening times. On Fridays, note if anything unusual has happened during the week that might have affected your child's behaviour. For weeks one and two, make a note of the listening times. By the end of week two or sooner, you should have settled on the best listening time for you and your child and should keep the same listening times throughout the study. The diary has instructions and examples.

MONDAY, DAY ONE

1. Start day one on a Monday with module number 1. Stay with your child to be sure they keep the headphones on while they engage in their activities. You may need to engage with them for the first week or two. Note the time you start listening. Generally parents find that best listening times are before school and after school.
2. Make sure your child has gone to the toilet.
3. Turn off distracting noises such as radio, television, computers and electronic games. Get out the activities box and see what your child is interested in doing while listening. Make sure they feel safe and comfortable.

4. Put the headphones on yourself first. Turn on the iPod and amplifier. Make sure the volume is at a comfortable level.
5. Put the headphones on your child or allow him to put them on himself. Be sure to place the headphones on the correct ears (R for right ear), as indicated on the headphones. Adjust the headphones so they will stay on easily.
6. Set a timer. When a listening session has finished, remove the headphones. Your daily listening session should not be more than 30 minutes

After two weeks, you should have established a comfortable routine at the same two times each listening day, Monday through Friday, for five consecutive days. You should continue to check on your child while they are listening in the following weeks, but you do not need to sit with them after you know for certain they will be able to play quietly while wearing the headphones for the entire listening session. When your timer indicates the listening session is over, be sure you or your child removes the headphones and puts them safely away for the next listening session.

If something totally unavoidable comes up and you miss a listening session, continue with the next number and make up any missed session(s) on the weekend. Do not skip ahead or go back, always continue listening to the next number.

Parent's Listening Diary

For the Autism Listening Study

The University of Edinburgh

IMPORTANT

DO NOT attempt to connect the iPod to your computer, or file loss may result.

This unit is equipped with copy protection. Do not attempt to copy files to or from your personal iPod to or from the iPod Nano that has been loaned to you for the autism listening study.

For the twenty-week duration of the listening protocol:

Your Listening Diary will allow you to easily know which module your child should be listening to and keep track of daily and weekly listening. Every Friday, make a note of anything that stood out during the week. Note the listening times you have chosen as your routine for the first two weeks, and after if the listening times change.

Please note what happened during the week that was different and might have affected behaviours, such as:

- Older sister had a party and noise was difficult for Alex.
- Owen had tummy trouble on Wednesday.
- We visited the paediatrician because of ___________.
- Callum started pre kindergarten on Tuesday this week.

- Grandparents came for a surprise visit and routine changed dramatically!
- Daddy away on business this week, especially difficult for Jake.

What if, in spite of your best efforts, you miss a listening session? Make it up on the weekend and just make a note of it in your diary. Always continue with the next number and make up sessions on the weekend if needed to complete the ten 15 minute sessions for the week. Do not skip ahead or go back, always continue listening to the next number. Then on the following Monday, you will be able to continue with the next ten numbered sessions shown in the listening diary.

You will receive an email each Friday with a link to the Autism Treatment Evaluation Checklist, ATEC for that week. Please set aside approximately 10 minutes to complete the ATEC each week. Tick the appropriate response that best indicates your child's behaviours for the week. We know there are always good and bad days, good and bad weeks. Don't worry about what you ticked the week before and don't worry about remembering everything. Just do the best you can. This will help us to see if there are trends or common changes after certain periods of time a child has listened.

Sample Listening Diary

Family ID No. McGregor9

Week One - Dates: 24 – 28 Feb

	Module	Time	Module	Time
Monday	1 ⑧	7:30	2 ⑧	4:00
Tuesday	3 ⑧	7:30	4 ⑧	4:45
Wednesday	5 ⑧	7:45	6 ⑧	4:45
Thursday	7 ⑧	7:45	8 ⑧	4:45
Friday	9 ⑧	7:45	10 ⑧	4:45
Catch up (if needed)				

⑧ Completed ATEC – https://www.survey.ac.uk/atec-1

Notes:

Week Two - Dates: 3 – 7 Mar

	Module	*Time*	*Module*	*Time*
Monday	11 ⑧	7:45	12 ⑧	4:45
Tuesday	13 ⑧	_______	14 ⑧	_______
Wednesday	15 ⑧	_______	16 ⑧	_______
Thursday	17 ⑧	_______	18 ⑧	_______
Friday	19 ⑧	_______	20 ⑧	_______

Catch up (if needed) Saturday No. 20 at 7:45

⑧ Completed ATEC – www.survey.ac.uk/atec-2

Notes:

The dog got sick and we had an emergency visit to the vet on Thursday afternoon. Afternoon listening just didn't happen! We made up that session on Saturday.

Our Listening Diary

Family ID No. ____________________________.

Week One - Dates:

	Module	*Time*	*Module*	*Time*
Monday	1 ⑧	_______	2 ⑧	_______
Tuesday	3 ⑧	_______	4 ⑧	_______
Wednesday	5 ⑧	_______	6 ⑧	_______
Thursday	7 ⑧	_______	8 ⑧	_______
Friday	9 ⑧	_______	10 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-1

Notes

Week Two - Dates:

	Module	*Time*	*Module*	*Time*
Monday	11 ⑧	_______	12 ⑧	_______
Tuesday	13 ⑧	_______	14 ⑧	_______
Wednesday	15 ⑧	_______	16 ⑧	_______

	Module	Time	Module	Time
Thursday	17 ⑧	_______	18 ⑧	_______
Friday	19 ⑧	_______	20 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-2

Notes:

Week Three - Dates:

	Module	*Time*	*Module*	*Time*
Monday	21 ⑧	_______	22 ⑧	_______
Tuesday	23 ⑧	_______	24 ⑧	_______
Wednesday	25 ⑧	_______	26 ⑧	_______
Thursday	27 ⑧	_______	28 ⑧	_______
Friday	29 ⑧	_______	30 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-3

Notes:

Week Four - Dates:

	Module	*Time*	*Module*	*Time*
Monday	31 ⑧	_______	32 ⑧	_______
Tuesday	33 ⑧	_______	34 ⑧	_______
Wednesday	35 ⑧	_______	36 ⑧	_______
Thursday	37 ⑧	_______	38 ⑧	_______

Friday	39 ⑧	_______	40 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-4

Notes:

Week Five - Dates:

	Module	*Time*	*Module*	*Time*
Monday	41 ⑧	_______	42 ⑧	_______
Tuesday	43 ⑧	_______	44 ⑧	_______
Wednesday	45 ⑧	_______	46 ⑧	_______
Thursday	47 ⑧	_______	48 ⑧	_______
Friday	49 ⑧	_______	50 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-5

Notes:

Week Six - Dates:

	Module	*Time*	*Module*	*Time*
Monday	51 ⑧	_______	52 ⑧	_______
Tuesday	53 ⑧	_______	54 ⑧	_______
Wednesday	55 ⑧	_______	56 ⑧	_______

Thursday	57 ⑧	_______	58 ⑧	_______
Friday	59 ⑧	_______	60 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-6

Notes:

Week Seven - Dates:

	Module	*Time*	*Module*	*Time*
Monday	61 ⑧	_______	62 ⑧	_______
Tuesday	63 ⑧	_______	64 ⑧	_______
Wednesday	65 ⑧	_______	66 ⑧	_______
Thursday	67 ⑧	_______	68 ⑧	_______
Friday	69 ⑧	_______	70 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-7

Notes:

Week Eight - Dates:

	Module	*Time*	*Module*	*Time*
Monday	71 ⑧	_______	72 ⑧	_______
Tuesday	73 ⑧	_______	74 ⑧	_______

Wednesday	75 ⑧	_______	76 ⑧	_______
Thursday	77 ⑧	_______	78 ⑧	_______
Friday	79 ⑧	_______	80 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-8

Notes:

Week Nine - Dates:

	Module	*Time*	*Module*	*Time*
Monday	81 ⑧	_______	82 ⑧	_______
Tuesday	83 ⑧	_______	84 ⑧	_______
Wednesday	85 ⑧	_______	86 ⑧	_______
Thursday	87 ⑧	_______	88 ⑧	_______
Friday	89 ⑧	_______	90 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-9

Notes:

Week Ten - Dates:

	Module	*Time*	*Module*	*Time*
Monday	91 ⑧	_______	92 ⑧	_______

Tuesday	93 ⑧	_______	94 ⑧	_______
Wednesday	95 ⑧	_______	96 ⑧	_______
Thursday	97 ⑧	_______	98 ⑧	_______
Friday	99 ⑧	_______	100 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-10

Notes:

Week Eleven - Dates:

	Module	*Time*	*Module*	*Time*
Monday	101 ⑧	_______	102 ⑧	_______
Tuesday	103 ⑧	_______	104 ⑧	_______
Wednesday	105 ⑧	_______	106 ⑧	_______
Thursday	107 ⑧	_______	108 ⑧	_______
Friday	109 ⑧	_______	110 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-11

Notes:

Week Twelve - Dates:

Dates: ______________	*Module*	*Time*	*Module*	*Time*
Monday	111 ⑧	_______	112 ⑧	_______
Tuesday	113 ⑧	_______	114 ⑧	_______
Wednesday	115 ⑧	_______	116 ⑧	_______
Thursday	117 ⑧	_______	118 ⑧	_______
Friday	119 ⑧	_______	120 ⑧	_______
Catch up (if needed)				

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-12

Notes:

Week Thirteen - Dates:

	Module	*Time*	*Module*	*Time*
Monday	121 ⑧	_______	122 ⑧	_______
Tuesday	123 ⑧	_______	124 ⑧	_______

Wednesday 125 ⑧ _______ 126 ⑧ _______

Thursday 127 ⑧ _______ 128 ⑧ _______

Friday 129 ⑧ _______ 130 ⑧ _______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-13

Notes:

Week Fourteen - Dates:

	Module	*Time*	*Module*	*Time*
Monday	131 ⑧	_______	132 ⑧	_______
Tuesday	133 ⑧	_______	134 ⑧	_______
Wednesday	135 ⑧	_______	136 ⑧	_______
Thursday	137 ⑧	_______	138 ⑧	_______
Friday	139 ⑧	_______	140 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-14

Notes:

Week Fifteen - Dates:

	Module	Time	Module	Time
Monday	141 ⑧	_______	142 ⑧	_______
Tuesday	143 ⑧	_______	144 ⑧	_______
Wednesday	145 ⑧	_______	146 ⑧	_______
Thursday	147 ⑧	_______	148 ⑧	_______
Friday	149 ⑧	_______	150 ⑧	_______
Catch up (if needed)				

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-15

Notes:

Week Sixteen - Dates:

	Module	Time	Module	Time
Monday	151 ⑧	_______	152 ⑧	_______

Tuesday	153 ⑧	_______	154 ⑧	_______
Wednesday	155 ⑧	_______	156 ⑧	_______
Thursday	157 ⑧	_______	158 ⑧	_______
Friday	159 ⑧	_______	160 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-16

Notes:

Week Seventeen - Dates:

	Module	*Time*	*Module*	*Time*
Monday	161 ⑧	_______	162 ⑧	_______
Tuesday	163 ⑧	_______	164 ⑧	_______
Wednesday	165 ⑧	_______	166 ⑧	_______
Thursday	167 ⑧	_______	168 ⑧	_______
Friday	169 ⑧	_______	170 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-17

Notes:

Week Eighteen - Dates:

	Module	*Time*	*Module*	*Time*
Monday	171 ⑧	_______	172 ⑧	_______
Tuesday	173 ⑧	_______	174 ⑧	_______
Wednesday	175 ⑧	_______	176 ⑧	_______
Thursday	177 ⑧	_______	178 ⑧	_______
Friday	179 ⑧	_______	180 ⑧	_______

Catch up (if needed)

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-18

Notes:

Week Nineteen - Dates:

	Module	*Time*	*Module*	*Time*

Monday	181 ⑧	_______	182 ⑧	_______
Tuesday	183 ⑧	_______	184 ⑧	_______
Wednesday	185 ⑧	_______	186 ⑧	_______
Thursday	187 ⑧	_______	188 ⑧	_______
Friday	189 ⑧	_______	190 ⑧	_______
Catch up (if needed)				

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-19

Notes:

Week Twenty - Dates:

	Module	*Time*	*Module*	*Time*
Monday	191 ⑧	_______	192 ⑧	_______
Tuesday	193 ⑧	_______	194 ⑧	_______
Wednesday	195 ⑧	_______	196 ⑧	_______

Thursday 197 ⑧ _______ 198 ⑧

____

Friday 199 ⑧ _______ 200 ⑧ _______

Catch up (if needed)

Notes:

Thank You and Congratulations –

You've completed the twenty week listening protocol!

But you're not completely finished yet…

Please complete these assessments online so we can see what changes may have occurred in the past 20 weeks.

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-20

⑧ Completed APSI – https://www.survey.ed.ac.uk/apsi-20

⑧ Completed AQ-child – https://www.survey.ed.ac.uk/aq-20

⑧ Completed Vineland-II. This paper assessment will be sent to you at the end of week 20. When you have completed answering questions in the Vineland-II, it should be returned to the investigator along with your Listening Diary.

You will be notified with instructions for returning your listening equipment. If you were in the listening group that had the selected listening programme, you will be asked to return all the equipment to the investigator at the University of Edinburgh.

If you were in the group who had the alternate listening programme, you will be asked to retain the headphones and return the iPod so it can be reloaded with the selected listening programme. It will be returned to you at 40 weeks, after the last assessment, so your child can experience the selected listening programme.

At 30 weeks and at 40 weeks, we will ask you to complete just the ATEC. This is called a follow up assessment, so we can see what will happen when your child has stopped listening. Will they lose skills, stay the same, or continue to improve in different areas? We will send an email reminder with the link for

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-30

⑧ Completed ATEC – https://www.survey.ed.ac.uk/atec-40

Appendix I

Autism Quotient – AQ-Child (3 pages)

Cambridge University Behaviour and Personality Questionnaire For Children (AQ - Child)

NOTE: This questionnaire is to be completed for your child in the University of Edinburgh Autism Listening Study. Please complete all three pages. It is important that **the same parent,** the one who spends the most time with the child, completes **all** the questionnaires for the study.

Family ID No: ______________________________

Today's Date: ______________________________

Person completing the questionnaire: ______________________________

Please answer each of the following questions about your child by ticking the box that reflects your answer to the question most appropriately. If there is any question that you do not feel able to comment on, please ask your son, daughter, or partner to answer.

	Definitely Agree	Slightly Agree	Slightly Disagree	Definitely Disagree
1. S/he prefers to do things with others rather than on her/his own.				
2. S/he prefers to do things the same way over and over again.				
3. If s/he tries to imagine something, s/he finds it very easy to create a picture in her/his mind.				
4. S/he frequently gets so strongly absorbed in one thing that s/he loses sight of other things.				
5. S/he often notices small sounds when others do not.				
6. S/he usually notices house numbers or similar strings of information.				
7. S/he has difficulty understanding rules for polite behaviour.				
8. When s/he is read a story, s/he can easily imagine what the characters might look like.				
9. S/he is fascinated by dates.				
10. In a social group, s/he can easily keep track of several different people's conversations.				
11. S/he finds social situations easy.				
12. S/he tends to notice details that others do not.				
13. S/he would rather go to a library than a birthday party.				

1

AQ-Child, page 2

	Definitely Agree	Slightly Agree	Slightly Disagree	Definitely Disagree
14. S/he finds making up stories easy.				
15. S/he is drawn more strongly to people than to things.				
16. S/he tends to have very strong interests, which s/he gets upset about if s/he can't pursue.				
17. S/he enjoys social chit-chat.				
18. When s/he talks, it isn't always easy for others to get a word in edgeways.				
19. S/he is fascinated by numbers.				
20. When s/he is read a story, s/he finds it difficult to work out the characters' intentions or feelings.				
21. S/he doesn't particularly enjoy fictional stories.				
22. S/he finds it hard to make new friends.				
23. S/he notices patterns in things all the time.				
24. S/he would rather go to the cinema than a museum.				
25. It does not upset him/her if his/her daily routine is disturbed.				
26. S/he doesn't know how to keep a conversation going with her/his peers.				
27. S/he finds it easy to "read between the lines" when someone is talking to her/him.				
28. S/he usually concentrates more on the whole picture, rather than the small details.				
29. S/he is not very good at remembering phone numbers.				
30. S/he doesn't usually notice small changes in a situation, or a person's appearance.				
31. S/he knows how to tell if someone listening to him/her is getting bored.				
32. S/he finds it easy to go back and forth between different activities.				
33. When s/he talks on the phone, s/he is not sure when it's her/his turn to speak.				

2

AQ-Child, page 3

	Definitely Agree	Slightly Agree	Slightly Disagree	Definitely Disagree
34. S/he enjoys doing things spontaneously.				
35. S/he is often the last to understand the point of a joke.				
36. S/he finds it easy to work out what someone is thinking or feeling just by looking at their face.				
37. If there is an interruption, s/he can switch back to what s/he was doing very quickly.				
38. S/he is good at social chit-chat.				
39. People often tell her/him that s/he keeps going on and on about the same thing.				
40. When s/he was in preschool, s/he used to enjoy playing games involving pretending with other children.				
41. S/he likes to collect information about categories of things (e.g. types of car, types of bird, types of train, types of plant, etc.).				
42. S/he finds it difficult to imagine what it would be like to be someone else.				
43. S/he likes to plan any activities s/he participates in carefully.				
44. S/he enjoys social occasions.				
45. S/he finds it difficult to work out people's intentions.				
46. New situations make him/her anxious.				
47. S/he enjoys meeting new people.				
48. S/he is good at taking care not to hurt other people's feelings.				
49. S/he is not very good at remembering people's date of birth.				
50. S/he finds it very to easy to play games with children that involve pretending.				

Appendix J

Autism Treatment and Evaluation Checklist (ATEC), 2 pages

Autism Treatment Evaluation Checklist (ATEC)

Autism Research Institute Bernard Rimland, PhD. And Stephen M. Edelson, PhD.

Family ID No: ____________________

Form completed by ____________________ Date completed ____________________

Please have the form completed by **the same person each time,** before you start the programme and each week after to the end of the 20-week listening protocol and at the 30 and 40 week follow up.

Please circle the letters to indicate how true each phrase is:

I. Speech/Language/Communication

N = Not true, S = Somewhat true, V = Very true

N S V 1. Knows own name
N S V 2. Responds to "No" or "Stop"
N S V 3. Can follow some commands
N S V 4. Can use one word at a time (No! Eat, Water, etc.)
N S V 5. Can use 2 words at a time (Don't want, Go home)
N S V 6. Can use 3 words at a time (Want more milk)
N S V 7. Knows 10 or more words
N S V 8. Can use sentences with 4 or more words
N S V 9. Explains what he/she wants
N S V 10. Asks meaningful questions
N S V 11. Speech tends to be meaningful/ relevant
N S V 12. Often uses several successive sentences
N S V 13. Carries on fairly good conversation
N S V 14. Has normal ability to communicate for his/her age

II. Sociability

N = Not descriptive, S = Somewhat descriptive, V = Very descriptive

N S V 1. Seems to be in a shell – you cannot reach him/her
N S V 2. Ignores other people
N S V 3. Pays little or no attention when addressed
N S V 4. Uncooperative and resistant
N S V 5. No eye contact
N S V 6. Prefers to be left alone
N S V 7. Shows no affection
N S V 8. Fails to greet parents
N S V 9. Avoids contact with others
N S V 10. Does not imitate
N S V 11. Dislikes being held/cuddled
N S V 12. Does not share or show
N S V 13. Does not wave "bye-bye"
N S V 14. Disagreeable/not compliant
N S V 15. Temper tantrums
N S V 16. Lacks friends/companions
N S V 17 Rarely smiles
N S V 18. Insensitive to other's feelings
N S V 19. Indifferent to being liked
N S V 20. Indifferent if parent(s) leave

ATEC, page 2

III. Sensory/Cognitive Awareness
N = Not descriptive, S = Somewhat descriptive, V = Very descriptive

N S V 1. Responds to own name	**N S V** 10. Aware of environment
N S V 2. Responds to praise	**N S V** 11. Aware of danger
N S V 3. Looks at people and animals	**N S V** 12. Shows imagination
N S V 4. Looks at pictures (and TV)	**N S V** 13. Initiates activities
N S V 5. Does drawing, colouring, art	**N S V** 14. Dresses self
N S V 6. Plays with toys appropriately	**N S V** 15. Curious, interested
N S V 7. Appropriate facial expression	**N S V** 16 Venturesome - explores
N S V 8. Understands stories on TV	**N S V** 17. "Tuned in" – Not spacey
N S V 9. Understands explanations	**N S V** 18. Looks where others are looking

IV. Health/Physical/Behaviour
***Use this code*: N = Not a problem, MI = Minor Problem,**
MO Moderate problem, S = Serious Problem

N MI MO S 1. Bed-wetting	**N MI MO S** 14. Sound-sensitive
N MI MO S 2. Wets pants/nappies	**N MI MO S** 15. Anxious/fearful
N MI MO S 3. Soils pants/nappies	**N MI MO S** 16. Unhappy/crying
N MI MO S 4. Diarrhea	**N MI MO S** 17. Seizures
N MI MO S 5. Constipation	**N MI MO S** 18. Obsessive speech
N MI MO S 6. Sleep problems	**N MI MO S** 19. Rigid routines
N MI MO S 7. Eats too much/too little	**N MI MO S** 20 Shouts or screams
N MI MO S 8. Extremely limited diet	**N MI MO S** 21. Demands sameness
N MI MO S 9. Hyperactive	**N MI MO S** 22. Often agitated
N MI MO S 10. Lethargic	**N MI MO S** 23. Not sensitive to pain
N MI MO S 11. Hits or injures self	**N MI MO S** 24. Hooked or fixated on certain objects/topics
N MI MO S 12. Hits or injures others	**N MI MO S** 25. Repetitive movements (stimming, rocking, etc.)
N MI MO S 13. Destructive	

ARI/Form
ATEC-1/11-99

Appendix K

Autism Parenting Stress Index - APSI

Autism Parenting Stress Index (APSI)

Family ID No: ________________________

Today's Date: ________________________

Person completing the questionnaire: ____

	Stress Ratings				
Please rate the following aspects of your child's health according to how much stress it causes you and/or your family by placing an X in the box that best describes your situation.	**Not stressful**	**Sometimes creates stress**	**Often creates stress**	**Very stressful on a daily basis**	**So stressful sometimes we feel we can't cope**
Your child's social development					
Your child's ability to communicate					
Tantrums/meltdowns					
Aggressive behavior (siblings, peers)					
Self-injurious behaviour					
Difficulty making transitions from one activitiy to another					
Sleep problems					
Your child's diet					
Bowel problems (diarrhea, constipation)					
Potty training					
Not feeling close to your child					
Concern for the future of your child being accepted by others					
Concern for the future of your child living independently					

Appendix L: Case Summaries, Group 1, mean scores in all Domains

Case Summaries - ATEC: Mean Scores

		Communication			Social Abilities			Behaviour		
	ID	Baseline	20 Weeks	Difference	Baseline	20 Weeks	Difference	Baseline	20 Weeks	Difference
Group 1	2	21			12			20		
	6	15	11	4.00	11	6	5.00	22	20	2
	8	5	4	1.00	2	0	2.00	14	9	5
	11	20	11	9.00	19	9	10.00	18	10	8
	13	8	8	0.00	11	15	-4.00	11	13	-2
	17	8	4	4.00	12	4	8.00	42	11	21
	24	7	2	5.00	13	8	5.00	32	16	16
	25	7	8	-1.00	9	6	3.00	26	17	9
	30	8	5	3.00	16	10	6.00	36	20	16
	33	3			14			19		
	35	10	10	0.00	18	13	5.00	33	23	10
	38	8	9	-1.00	13	16	-3.00	21	14	7
	42	11	9	2.00	23	14	9.00	25	12	13
	44	10	11	-1.00	12	13	-1.00	24	13	11
	46	6	5	1.00	18	11	7.00	26	11	15
	49	21	16	5.00	14	13	1.00	47	22	25
	54	2	2	0.00	5	4	1.00	21	8	13
	61	18	18	0.00	11	9	2.00	15	18	-3
	Total	10.44	8.31	1.9375	12.94	9.44	3.5000	25.11	14.81	11.0000

Appendis L: Case Summaries Group 2, Mean Scores in all Domains

Case Summaries - ATEC: Mean Scores

		Communication			Social Abilities			Behaviour		
	ID	Baseline	20 Weeks	Difference	Baseline	20 Weeks	Difference	Baseline	20 Weeks	Difference
Group 2	3	15	13	2.00	12	8	4.00	18	3	15
	7	10	9	1.00	13	12	1.00	11	6	5
	12	11	12	-1.00	15	18	-3.00	41	38	3
	15	18	19	-1.00	8	17	-9.00	7	15	-8
	18	13	12	1.00	11	9	2.00	6	3	3
	20	8	11	-3.00	12	15	-3.00	29	31	-2
	22	11			25			33		
	27	8	1	7.00	7	0	7.00	23	1	22
	31	13			11			11		
	34	6	9	-3.00	3	13	-10.00	23	27	-4
	37	4	1	3.00	7	8	-1.00	7	2	5
	41	18	13	5.00	19	17	2.00	18	19	-1
	43	4			11			21		
	47	10	1	9.00	18	14	4.00	29	23	6
	51	26	22	4.00	15	5	10.00	19	15	4
	53	3	4	-1.00	11	8	3.00	22	10	12
	56	14	13	1.00	33	22	11.00	48	33	15
	60	4	6	-2.00	19	14	5.00	32	27	5
	Total	10.89	9.73	1.4667	13.89	12.00	1.5333	22.11	16.87	5.3333

Appendis L: Case Summaries Group 3, Mean Scores in all Domains

Case Summaries - ATEC: Mean Scores

		Communication			Social Abilities			Behaviour		
	ID	Baseline	20 Weeks	Difference	Baseline	20 Weeks	Difference	Baseline	20 Weeks	Difference
Group 3	1	25	24	1.00	32	30	2.00	46	39	7
	9	9	10	-1.00	8	7	1.00	26	25	1
	14	10	11	-1.00	14	16	-2.00	18	14	4
	16	12	10	2.00	15	13	2.00	17	13	4
	23	25			13			25		
	26	9	10	-1.00	19	21	-2.00	24	38	-14
	28	8	8	0.00	13	13	0.00	37	23	14
	32	8	10	-2.00	19	20	-1.00	26	18	8
	36	4	4	0.00	11	17	-6.00	16	17	-1
	39	8	6	2.00	15	10	5.00	13	14	-1
	40	7	7	0.00	10	14	-4.00	35	36	-1
	45	6	0	6.00	7	6	1.00	12	7	5
	52	10			21			21		
	55	8	7	1.00	16	16	0.00	22	21	1
	59	5	4	1.00	13	9	4.00	38	17	21
	63	11	13	-2.00	11	18	-7.00	30	44	-14
	Total	10.31	8.88	.4286	14.81	15.00	-.5000	25.38	23.29	2.4286
Total		10.56	8.98	1.3111	13.85	12.02	1.6000	24.15	18.13	6.4444